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US005779704A

United States Patent [19]

Kim

[11] Patent Number: 5,779,704

[45] Date of Patent: Jul. 14, 1998

[54] **BI-DIRECTIONAL UNIVERSAL DYNAMIC COMPRESSION DEVICE**

[76] Inventor: **Andrew C. Kim**, 30213 Del Rey Rd., Temecula, Calif. 92591

[21] Appl. No.: **674,784**

[22] Filed: **Jul. 3, 1996**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 618,366, Mar. 19, 1996.

[51] **Int. Cl.**[6] **A61B 17/72**

[52] **U.S. Cl.** **606/64**; 606/73

[58] **Field of Search** 606/62, 63, 64, 606/66, 67, 68, 69, 70, 71, 72, 73, 105

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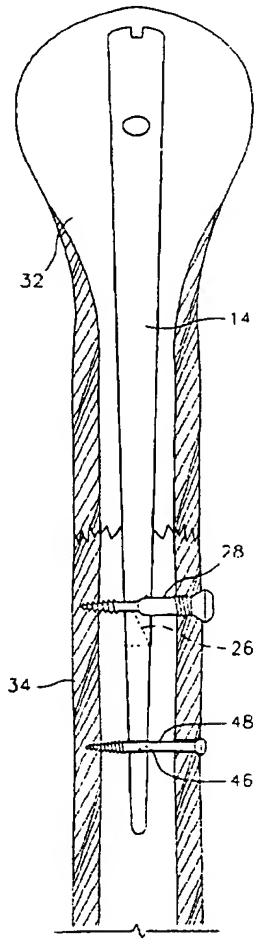
Primary Examiner—Michael Buiz
Assistant Examiner—David O. Reip
Attorney, Agent, or Firm—Baker, Maxham, Jester & Meador

[57] **ABSTRACT**

A compression interlocking system for stabilizing long bone fractures, comprises an elongated intramedullary rod having a proximial end, a distal end and a longitudinal axis, the rod adapted for extending within a bore generally parallel to a longitudinal axis of a long bone from a proximal end of the bone to beyond a fracture of the bone, a threaded member for fixing the proximal end of the rod to a first portion of a bone having a fracture, a second member for fixing the distal end to a second portion of the bone having the fracture, and a cam for moving the second portion of the bone toward the first portion of the bone for closing and applying compression to the fracture.

16 Claims, 5 Drawing Sheets



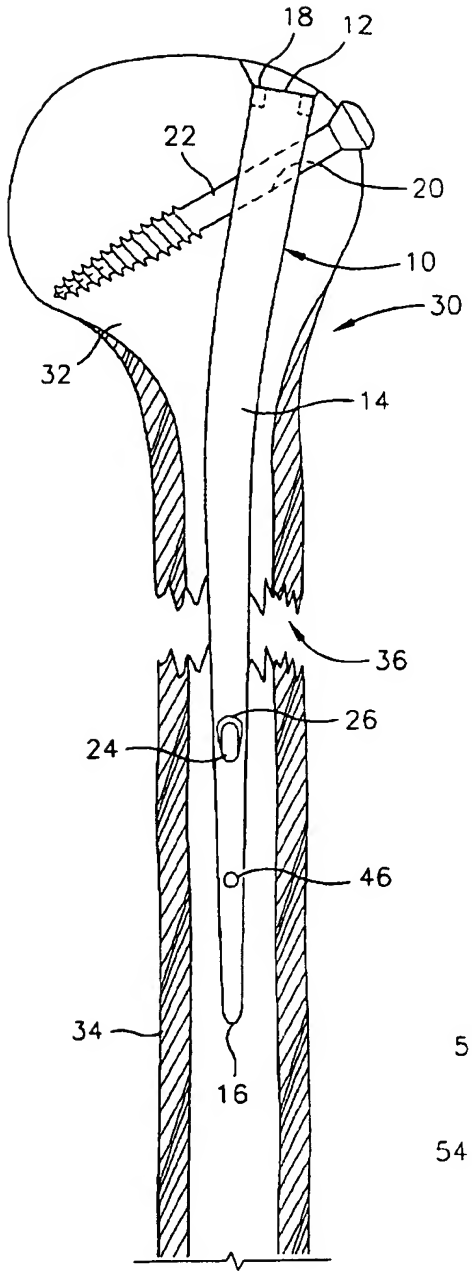


FIG. 1

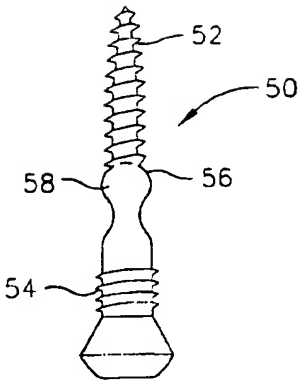


FIG. 12

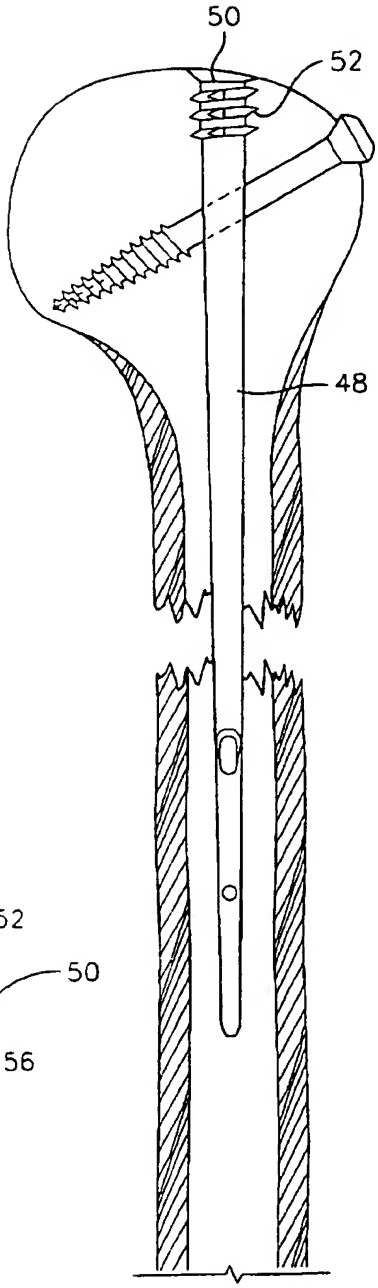


FIG. 11

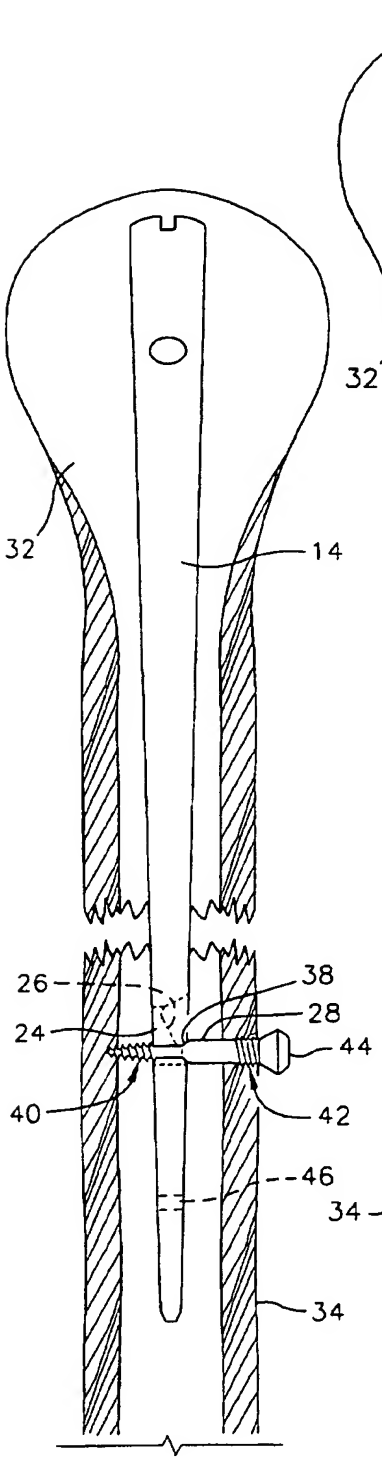
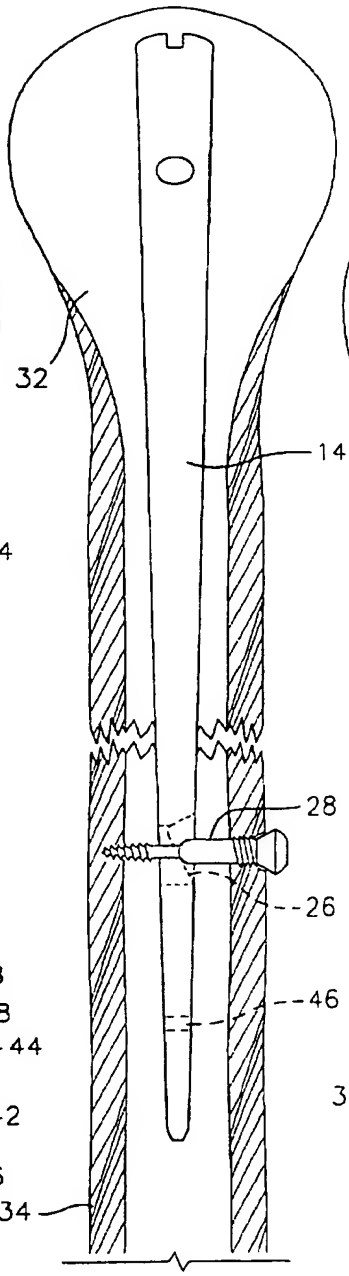


FIG. 2



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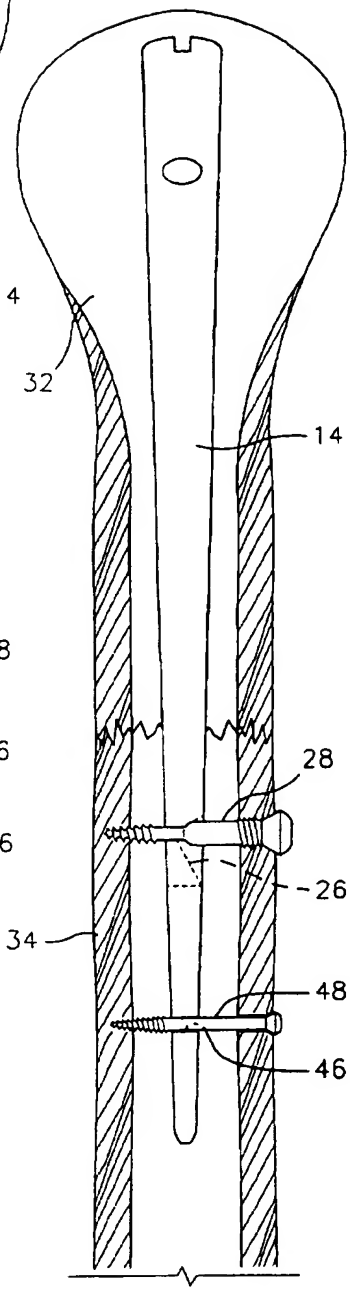

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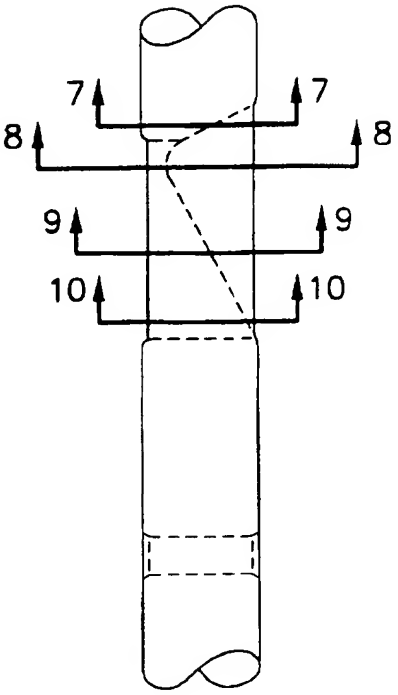


FIG. 5

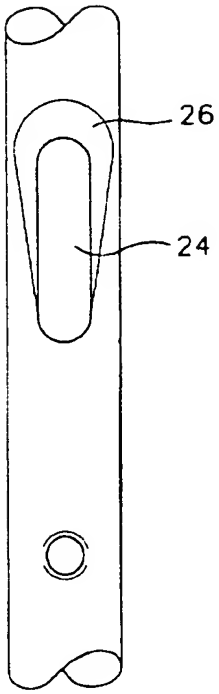
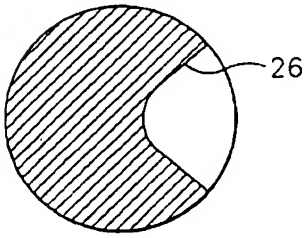


FIG. 6



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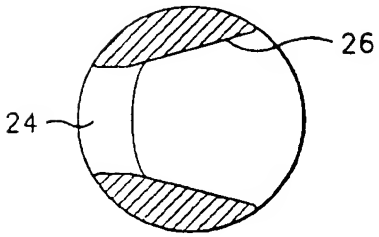

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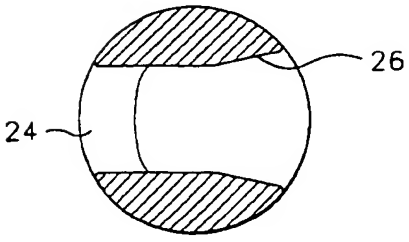

FIG. 9

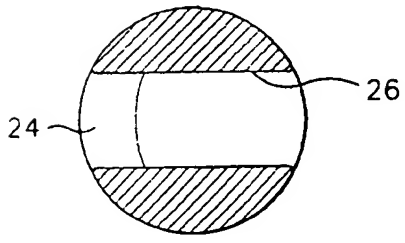

FIG. 10

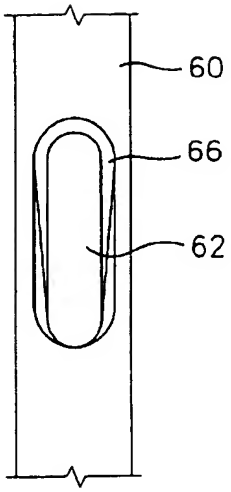

FIG. 13

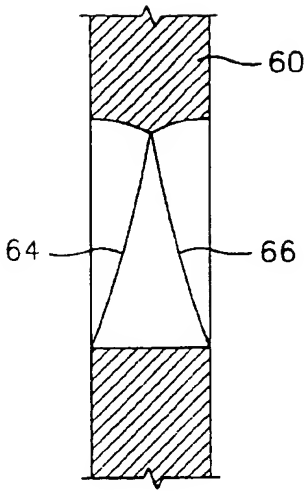

FIG. 14

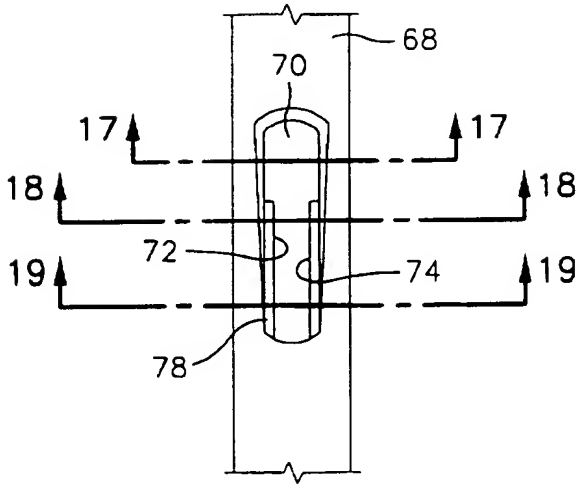

FIG. 15

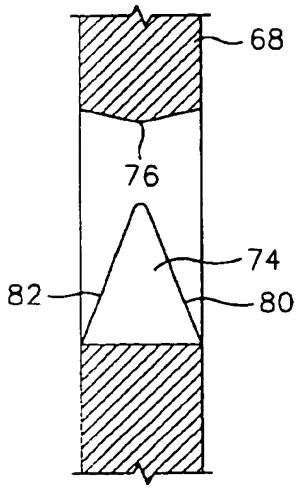

FIG. 16

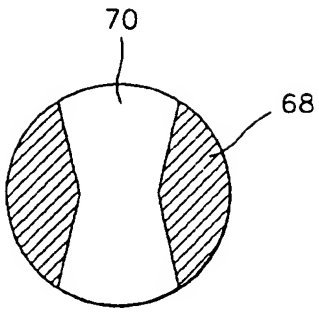

FIG. 17

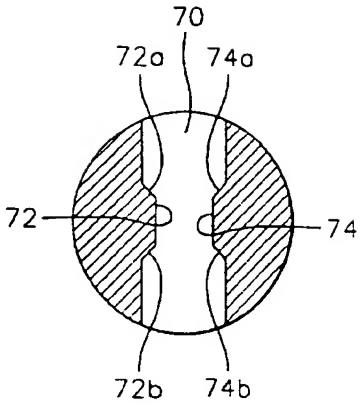

FIG. 18

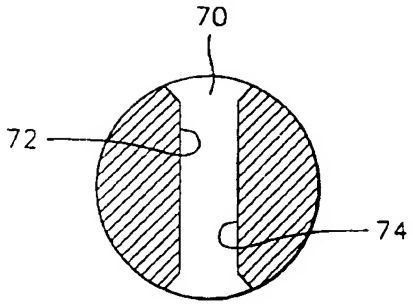

FIG. 19

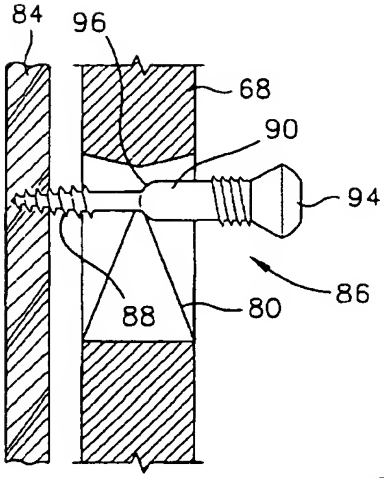

FIG. 20

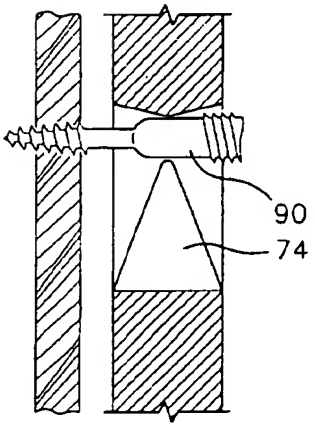

FIG. 22

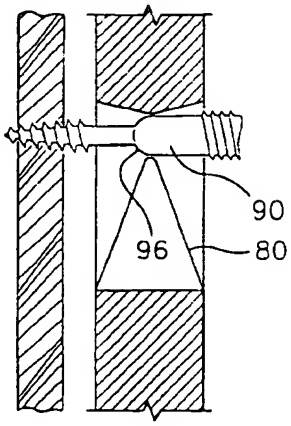

FIG. 21

BI-DIRECTIONAL UNIVERSAL DYNAMIC COMPRESSION DEVICE

REFERENCE TO RELATED APPLICATION

This is a Continuation-in-part of application Ser. No. 08/618,366 filed Mar. 19, 1996, and entitled "UNIVERSAL DYNAMIC COMPRESSION DEVICE FOR INTRAMEDULLARY SYSTEM".

BACKGROUND OF THE INVENTION

The present invention relates to medical devices and pertains particularly to an improved rod fixation system for fractures in long bones.

Fractures in long bones in the human body can properly heal only if the two portions of the fractured bones are properly positioned and fixed relative to each other. Such fractures are frequently assisted in their mending by utilizing either an external or internal splints Internal splints are preferred for most fractures and consist of an elongated intramedullary rod or nail inserted in a bore extending along the axis of the bone and secured by screws to tie the two parts of the fractured bone together until healing can occur. A major difficulty with prior art devices in the case of humerus is that non-union or delayed union frequently occurs. I have found that part of the reason is that the applied force is tensile force rather than compression required to force the two parts of the fractured bone together to enable mending.

In my prior patent, U.S. Pat. No. 5,480,402, entitled "Shoulder Compression Interlocking System", I disclosed an improved rod and interlocking system which improved the stabilization of bone fractures. However, that structure was unable to apply the necessary compressive forces discovered to be necessary.

In fracture healing, there are two basic requirements: osteoconduction and osteoinduction. Osteoconduction is a physical, mechanical requirement. Contact or continuity of bone ends is important for fracture healing. Osteoinduction is the consideration of biological biomechanical induction of bone healing and bone formation. Blood circulation, soft tissue preservation, Wolf's law are important considerations for osteoinduction.

Nonsurgical treatment with cast application stresses osteoinduction aspect in fracture healing. Surgical fixation, such as plate fixation stresses more of the osteoconduction aspect. In this method, a small gap in the fracture fixation can be very harmful with danger of nonunion developing. Successful healing of the callus tissue is affected by the stress it received (Perren). Stress is a function of the following factors:

$$\text{Stress} \propto \frac{\Delta l}{l} \qquad \Delta l = \text{motion in the gap} \qquad l = \text{width of the gap}$$

Therefore, a small gap in internally fixed fracture imposes greater danger of developing nonunion than a nonoperative fracture with a larger gap. Under- such circumstances, there is already less reliance on osteoinduction and the benefit of osteoconduction is compromised by micromotion significant in proportion to the size of the gap.

Intramedullary rod fixation without interlocking provides internal splint effect. It gives closer reduction to provide better anatomical alignment and osteoconduction effect. Weight bearing allows compression of fracture site narrowing gaps. The rod still allows transfer of Wolf's stress and

osteoinduction. However, intramedullary rod system does not provide torsional stability. Therefore interlocking intramedullary fixation system was devised to compensate for torsional stability or to prevent excessive shortening when a comminuted fracture did not provide cortical stability.

Interlocking intramedullary rod systems are currently widely used. As a result, the interlocking system, though it may provide rotational stability, usually creates fixed gap at the fracture site. The gap bypasses the stress from the bone to the implant sometimes causing implant failure such as screw or rod breakage. Delayed union is the frequent result.

Interlocking rod fixation does not completely eliminate micro motion due to an oscillating or windshield wiper effect. To eliminate the windshield wiper effect, some manufacturers made two plane interlocking in the distal tibia. The two plane interlocking requires more soft tissue disturbance and increases risks of injury.

A more ideal system would be an interlocking rod with minimal micromotion but with compression or elimination of any gap. The benefits of my new invention in comparison can be summarized as follows:

1) Narrows the fracture gap to the point of contact providing osteoconduction.
2) Eliminates micromotion.
3) Provides dynamic compression at the fracture site, and therefore, osteoinduction through Wolf's stress.
4) Shares the stress through the fractured long bone between the bone and the implant rather than having the implant take up the entire stress. As a result, implant failure such as rod or screw breakage will be minimized.
5) Reduces motion at the distal interlocking (windshield wiper motion) by internal locking of the rod with this newly designed compression screw. Therefore, with one plane approach it achieves the benefit of two plane stability.

The aforementioned parent application solved many of the above problems by providing an improved intramedullary system for providing compression to the fracture site to help bring about faster healing with less implant failure. However, that system suffers from the inability to apply it universally, i.e. equally to opposite sides, such as the right or left side.

It is therefore desirable to have a long bone fixation device that is simple and universally applicable to both sides.

There is a need for an improved universal intramedullary system for providing compression to the fracture site to help bring about faster healing with less implant failure.

In some applications it may be desirable to insert the compression lag screw from one or more different sites, such as adjacent sides or opposite sides. This could be particularly advantageous where the rod is curved and would enable a single rod to service in many applications. Suitable modifications to the rod could be made either by providing an additional hole with a cam, or by providing an additional cam in a common hole. The advantage of using a single cam for each of two or more holes is that the slope of the cam can be greater with a single cam from one side of the hole. This greater slope could have the effect of increasing the compression on the bone into which the rod is installed. It could also enable the provision of a greater length to the slot and cam to accommodate larger displacement of the bone sections. It also enables the provision of the cammed compression slot at any number of different angles about and positioned along the length of tile rod.

SUMMARY OF THE INVENTION

It is therefore a primary object of the present invention to provide a more universal and effective long bone fixation device.

In accordance with a primary object of the present invention, a long bone fixation device wherein interlocking screws of rod screw combination have a stepped diameter with a semi-spherical shoulder cooperative with cam slots on opposite sides of the rod to provide a universal system to more effectively apply compression to the fracture site to enhance healing.

BRIEF DESCRIPTION OF THE PREFERRED EMBODIMENTS

The above and other objects and advantages of the present invention will become apparent from the following description when read in conjunction with the accompanying drawings wherein:

FIG. 1 is a front elevation view of an exemplary preferred embodiment of the invention shown in position for use;

FIG. 2 is a side elevation view of the embodiment of FIG. 1 showing the invention in a first stage of applying compression to a fracture;

FIG. 3 is a view like FIG. 2 showing the invention in a second stage of applying compression to a fracture;

FIG. 4 is a view like FIG. 2 showing the invention in a final stage of applying compression to a fracture;

FIG. 5 is an enlarged partial side elevation view of the cam area of the rod;

FIG. 6 is an enlarged partial front elevation view of the cam area of the rod;

FIG. 7 is a section view taken generally along line 7—7 of FIG. 5;

FIG. 8 is a section view taken generally along line 8—8 of FIG. 5;

FIG. 9 is a section view taken generally along line 9—9 of FIG. 5;

FIG. 10 is a section view taken generally along line 10—10 of FIG. 5;

FIG. 11 is a view like FIG. 1 of an alternate embodiment of the invention;

FIG. 12 is a side elevation view of an alternate embodiment of a lag screw;

FIG. 13 is a front elevation view showing an alternate embodiment with a bidirectional cam and slot arrangement;

FIG. 14 is a section view taken generally on line 14—14 of FIG. 13;

FIG. 15 is a view like FIG. 13 of a further embodiment of the invention;

FIG. 16 is a view like FIG. 14 of the embodiment of FIG. 15;

FIG. 17 is a section view taken on line 17—17 of FIG. 15;

FIG. 18 is a section view taken on line 18—18 of FIG. 15;

FIG. 19 is a view taken on line 19—19 of FIG. 15;

FIG. 20 is a side elevation view in section showing a rod positioned in a bone structure with a lag screw in a position of partial insertion;

FIG. 21 is a view like FIG. 20 showing the lag screw in a further advanced position of insertion; and

FIG. 22 is a view like FIG. 21 showing the lag screw in the fully inserted position.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is directed to an improved intramedullary rod fixation system for long bones for fixation of bones that have been fractured. Referring specifically to FIG. 1 of the drawings there is illustrated a front elevation view in section of a bone having an exemplary embodiment of the rod designated generally by the numeral 10, in accordance with the invention positioned therein. The rod (sometimes called pin or nail in the art) comprises an elongated unitary or integral hollow body having a head or proximal end 12 an elongated intermediate body portion 14 and a distal tip 16. The head end 12 may be formed by a suitable threaded bore and is provided with alignment lugs 18. These lugs are used in conjunction with a guide fixture for alignment for drilling and insertion of lag screws as is known in the art. The rod 10 is provided with one or more transverse screw receiving bores 20 near the proximal end for receipt of fixation lag screws 22. It may be similarly provided with one or more similar bores near the distal tip so as to be positioned beyond the fracture which it is to fix.

An oblong transverse bore 24 is formed in an intermediate position of the shank of the rod 14 at a position to be beyond a fracture in a bone in which the rod is mounted. Surrounding the bore or hole 24 is a cam 26 which cooperates with a shoulder on a specially constructed lag screw 28 for applying compression to a fracture between two portions of a fractured bone. The cam 26 is formed by a sloping surface surrounding the hold or bore 24. The rod, as illustrated in FIG. 1 is inserted into a longitudinally extending bore formed along the center axis of a long bone designated generally by the numeral 30. The bone, as illustrated, has an upper portion 32 and a lower portion 34 which has been fractured from the upper portion along a fracture 36. In the illustrated embodiment the rod 14 has been inserted along the bone in a conventional fashion. The present invention is designed to be utilized in any long bone of the body, such as the humerus, femur, tibia and other bones. The rod preferably has a cannula or elongated longitudinal bore to enable the use of a guide wire (not shown) in a conventional fashion.

Referring to FIG. 2 of the drawing a side elevation view in section of the embodiment of FIG. 1 showing the compression mechanism of the present invention is illustrated. As illustrated, the bore 24 extends across the rod and is oblong or has a somewhat oval configuration defining a somewhat slot like structure extending along the longitudinal axis of the rod 14. Surrounding the bore is a sloping cam track 26 which forms a wedge-like cam sloping inward in the longitudinally upward direction, or toward the head of the rod or pin. This track cooperates with a shoulder 38 on the stepped diameter lag screw 28 between a smaller diameter portion 40 at the distal end and a larger diameter portion 42 near the head 44 of the lag screw. The forward or distal end of the lag screw 28 is formed with self-tapping threads to aid in threading the screw into the bone portion 34. The lag screw is also formed with self-tapping threads on the larger portion 42 at the head and preferably with a non-threaded portion adjacent the shoulder on the head side. The head 44 is preferably formed with a hex socket for engagement with an Allan wrench.

In operation, once the rod 14 has been inserted into a bone 30, as shown in FIG. 1, a typical guide instrument is utilized to align a suitable drill with bores at the upper end of the rod, such as bore 20 to enable the drilling of holes for insertion of lag screw 22. Additional screws may be utilized in the arrangement, shown for example in my prior patent, identified above. Once the rod is anchored in the upper portion 32 of the bone 30 the lower bone is properly positioned and properly oriented. The guide fixture is then utilized to locate and drill a hole in the bone portion intersecting the bore 24.

as shown in FIG. 2. Preferably the hole through the bone will intercept the oblong bore 24 at its lower most end so that when screw 28 is inserted, ample room for biasing and movement of the bone and screw upward to establish compression in the fracture will be provided. As will be appreciated, the screw 28 having a step diameter, a first drill for portion 40 will be drilled through the bone in alignment with the lower most end of bore 24. Thereafter, a larger hole will be made up to the edge of the rod 14. A preferred method is the utilization of a cannulated or hollow second diameter bore drill that fits over the first drill utilizing the first drill as a guide to maintain precise alignment.

Once the hole is made into the bone, the screw 28 is inserted through hole 24 and threaded into the far side of the bone. As the screw threads into the bone, the shoulder 38 of screw 28 engages and biases against cam surface 26. As the screw 28 moves further inward, it rides upward on the slope 26 carrying the bone portion 34 there along to further move the bones closer together in the area of the fracture 34, as shown in FIG. 3. The screw 28 is threaded in until the lower bone portion moves into engagement with the upper portion 14 and a suitable compression is established. In the ideal position, a suitable compression is reached as the screw approaches or nears the bottom of the slope of the cam 26, as shown in FIG. 4.

The rod 14 may have a curved configuration, as illustrated, or may have a straight configuration depending on its application. The dimensions of the rod including length, diameter, number and position of holes may also vary, depending on the requirements.

Referring to FIG. 11, further embodiment is illustrated showing a straight rod 48 and utilizing a fixation thread 52 at the top or head 50, as illustrated. The straight rod can be rotated to fix it in the bone by threads 52, which are preferably self-tapping. Additional bores may be provided in the rod in any number of positions and angles, such as disclosed in my prior patent. The additional bores may be positioned to receive conventional lag screws to more securely fix the bone portions to the rod.

Referring to FIG. 12, an alternate embodiment of a compression lag screw designated generally by the numeral 50 is illustrated. The screw has a reduced diameter threaded forward portion 52 and an enlarged threaded rear portion 54. A bearing shoulder 56 is formed by a spherical portion 58 intermediate the two different diameter portions of the lag screw with the larger diameter portion down to provide a greater spherical surface. This construction may be preferred in many applications.

Referring to FIGS. 13 and 14, a rod 60 is formed with a double cam elongated through slot 62 having opposing cam surfaces 64 and 66. The cam surfaces 64 and 66 are directly opposed to one another at opposite ends of the bore 62. The cam surfaces, as will be appreciated, have a depth of only ½ of the diameter of the rod 60 with a length equal to the height or length of the slot 62. With this arrangement, a lag screw such as that illustrated at 28 in FIGS. 2–4, or that in FIG. 12 may be inserted from either side of the rod 60. Thus, the rod becomes universal in the sense that it can be utilized for the left or right side, for example. The depth of the cam, however, may be on the order of about ½ that of a single cam bore, as in the previous embodiments. This results in a shallower slope cam surface, thus resulting in lower (lesser) forces on the bone structure to cam the bone structures together.

Referring to FIGS. 15 and 16, an alternate embodiment is illustrated wherein a rod 68 is formed with an oblong through slot 70 having a pair of opposed cams formed by triangular cam structures 72 and 74. The cam structure 72 and 74 terminates short of the top wall 76 of the bore 70, thereby leaving an opening through which the lag screw or bolt may extend, as will be subsequently explained. This cam structure provides a steeper slope than that of FIGS. 13 and 14, thereby providing greater compression on the bone structure. This structure may also provide substantially the same distance of movement of the bone structure bringing the two bone portions together.

The cam structure 72 forms two cam surfaces, only one of which, 78, is illustrated. The cam structure 74 similarly forms two cam surfaces, 80 and 82 as shown in FIG. 16, which may be engaged by a lag screw from opposite sides of the rod.

Referring to FIGS. 17, 18 and 19, cross-sectional areas of the through bore with the cam structure are illustrated. As is illustrated in FIGS. 17, the upper portion of the bore 70 above the cam structure provides an opening for substantial passage of the lag screw, as will be described. It will also be appreciated, as shown in FIG. 17, that the slot opens outward at both sides to accommodate minor deviations of the direction of the screw at insertion. Thus, minor deviations of the rod about its axis are accommodated allowing the screw to be inserted into the cross slot.

Referring to FIG. 18, a top portion of the cam surfaces is illustrated, showing the cam and its projection inward into the cross slot. The camming surfaces 72*a* and 72*b* and 74*a* and 74*b* are shown angled toward the sidewalls of the slot. However, they may extend straight in toward the wall (i.e. at 90°).

FIG. 19 illustrates a cross-section of a lower portion of the slot and cam combination. It would have the same slope and angle to the walls.

Referring to FIG. 20, a cross-sectional view of a rod 68 inserted into a bone, a portion of which, 84, is illustrated. A lag screw designated generally at 86, has a distal reduced diameter threaded portion 88 and a proximal larger diameter portion 90 having a threaded section 92 adjacent a head 94. A shoulder 96 of a semispherical configuration forms a transition between the larger diameter portion 90 and the smaller diameter portion 88. The shoulder 96 engages the laterally adjacent cam surfaces 78 and 80 and cams the bone section 84 upward relative to the rod 68. This closes and applies a compression to the fracture, as previously described with respect to other embodiments.

As shown in FIG. 20, the screw 90 has reached substantially the end of the cam surfaces with a little further camming distance to go.

Referring to FIG. 21, the screw 86 has reached the end of the cam surface 80 thereby reaching the end of movement of the bone section relative to the rod 68.

Referring to FIG. 22, the lag screw portion 90 has extended beyond the tip of the cam 74 and partially across the bore, thereby locking the bone and rod together. Thus, it can be seen that there are described embodiments wherein a lag screw can be inserted from different angles about the axis of the rod, thereby providing a universal compression assembly.

While I have illustrated and described my invention by means of specific embodiments, it is to be understood that numerous changes and modifications may be made therein without departing from the spirit and the scope of the invention as defined in the appended claims.

I claim:

1. A compression interlocking system for stabilizing long bone fractures, comprising:

elongated intramedullary rod means having a proximal end, a distal end and a longitudinal axis, said rod means adapted for extending within a bore generally parallel to a longitudinal axis of a long bone from a proximal end of the bone to beyond a fracture of the bone;

first means for fixing said proximal end to a first portion of a bone having a fracture;

second means for fixing said distal end to a second portion of the bone having the fracture; and

compression means associated with said second means and accessible from at least two sides of said rod for moving said second portion of the bone toward said first portion of the bone for applying compression to the fracture, said compression means comprising cam means on said two sides of said rod and a lag screw having shoulder means for engaging said cam.

2. A system according to claim 1 wherein said second means comprises a transverse bore in said rod, and a lag screw for extending through said bore and anchoring in said second portion of said bone.

3. A system according to claim 1 wherein said cam comprises a sloping surface surrounding said bore in said rod.

4. A system according to claim 3 wherein said bore is elongated slot-like for enabling said screw and said bone portion to move longitudinally of said rod.

5. A system according to claim 1 wherein said second means comprises a transverse bore in said rod, said bore having an elongated diameter longitudinally of said rod, and a lag screw for extending through said bore and anchoring to said bone portion.

6. A system according to claim 5 wherein said compression means comprises a cam on said rod and said lag screw having rounded shoulder means for engaging said cam.

7. A system according to claim 6 wherein said cam comprises an elongated sloping surface surrounding said elongated bore in said rod.

8. A system according to claim 6 wherein said first means for fixing said proximal end comprises self-tapping threads on said proximal end.

9. A system according to claim 1 wherein said first means for fixing said proximal end comprises self-tapping threads on said proximal end.

10. A compression interlocking system for stabilizing long bone fractures, comprising:

elongated intramedullary rod means having a proximal end, a distal end and a longitudinal axis, said rod means adapted for extending within a bore generally parallel to a longitudinal axis of a long bone from a proximal end of the bone to beyond a fracture of the bone;

proximal fixing means for fixing said proximal end to a first portion of a bone having a fracture;

a transverse bore in the rod means for positioning in a second portion of the bone at a position beyond the fracture from said proximal end, said transverse bore having a predetermined diameter and a configuration enabling a lag screw to move longitudinally of the rod when viewing in elevation view of the rod means;

cam means on said rod adjacent said bore for engaging and camming a lag screw along from either side of said axis of said rod means so that said lag screw may be moved along said axis relative to said rod; and

a stepped diameter lag screw for extending across said second portion and through said transverse bore, said lag screw having a stepped diameter with a forward end having a diameter less than said predetermined diameter and a rear end greater than said predetermined diameter, and a shoulder between said diameters for engaging said cam means on said rod.

11. A system according to claim 10 wherein said bore has an elongated diameter disposed longitudinally of said rod, and said cam comprises an elongated sloping surface surrounding said elongated bore, said lag screw having rounded shoulder means for engaging said cam.

12. A system according to claim 11 wherein said proximal fixing means for fixing said proximal end comprises self-tapping threads on said proximal end.

13. A system according to claim 10 wherein said proximal fixing means for fixing said proximal end comprises self-tapping threads on said proximal end.

14. A compression interlocking rod for use in stabilizing long bone fractures, comprising:

elongated intramedullary rod member having a proximal end, a distal end and a longitudinal axis, said rod member adapted for extending generally parallel to a longitudinal axis within a bore of a long bone from a proximal end of the bone to beyond a fracture of the bone;

a first transverse bore means for receiving a screw for fixing said proximal end to a first portion of a bone having a fracture;

a second transverse bore means for fixing said distal end to a second portion of the bone having the fracture; and

compression cam means associated with each end of said second transverse bore means and engagable from either side of said rod by a lag screw having a shoulder for moving said second portion of the bone toward said first portion of the bone for applying compression to the fracture.

15. A rod according to claim 14 wherein said compression cam means comprises a cam on said rod and said lag screw having rounded shoulder means for engaging said cam.

16. A rod according to claim 14, further comprising a stepped diameter lag screw for extending across said second portion and through said second transverse bore, said lag screw having a stepped diameter with a forward end having a diameter less than said transverse bore and a rear end greater than said transverse bore, and a shoulder between said diameters for engaging said cam means on said rod.

* * * * *

Aug. 14, 1945. E. A. MILLER 2,382,019

COMPOUND SCREW

Filed May 2, 1944

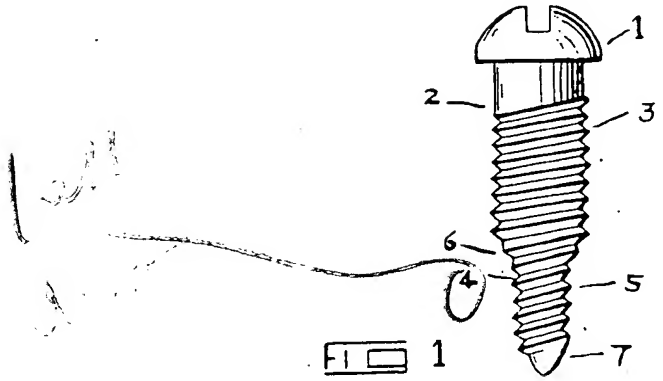

FIG 1

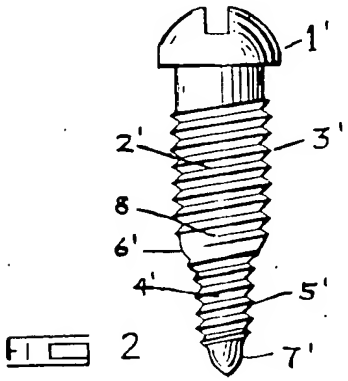

FIG 2

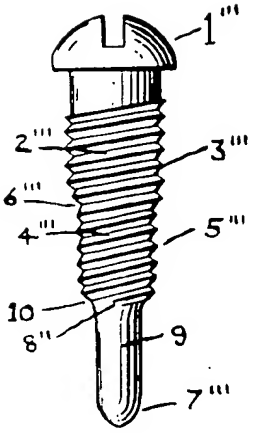

FIG 4

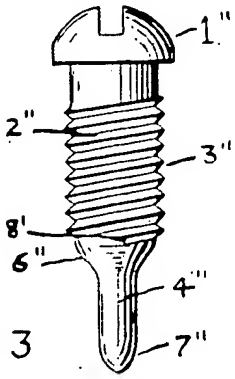

FIG 3

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BY

George Henry Elwell ATTY

Patented Aug. 14, 1945 2,382,019

UNITED STATES PATENT OFFICE

2,382,019

COMPOUND SCREW

Edwin August Miller, Fairfield, Conn.

Application May 2, 1944, Serial No. 533,680

1 Claim. (Cl. 85—41)

This invention relates to compound screws and more particularly to screws axially provided integrally with plural shank sections of which the lower section is of a lesser diameter than that of the next upper one.

The applicant is aware that the previous art discloses screws having gimlet terminals, and conical and pin points, but each of terminals and points thus shown is a part of the ordinary formation of screw having but a single shank.

Referring to the accompanying drawing, the Figure 1 illustrates a compound screw with a conoidal terminal and of which the thread of the lower section is an unbroken continuance of the thread of the upper section; Figure 2 illustrates a similar compound screw, but of which the thread of the upper section terminates in a cutting shoulder; Figure 3 illustrates another similar compound screw having the thread of the upper section terminate in a cutting shoulder, but the lower section being unthreaded and having a conoidal terminal; and Figure 4 illustrates still another similar compound screw, but of three sections of which the intermediate section comprises a threaded shank of a lesser diameter than that of the uppermost section, and of a greater diameter than that of the lowest section.

With more particular reference to the accompanying drawing, the numeral 1 designates the head of the compound screw, which head may be as illustrated in the various figures, or may be of any other desired form, or entirely omitted. In the Figure 1 the upper shank section 2 of substantially cylindrical form is provided with the screw thread 3. The numeral 4 designates the lower shank section of lesser diameter than that of the shank section 2 and also of substantially cylindrical form. The section 4 is peripherally provided with the screw thread 5 of the same number of convolutions to the inch with which the section 2 is provided, the thread of the section 4 being a continuation of the convolutions of thread 5 of the section 2. The periphery of the compound screw structure at place of association of the sections 2 and 4 is of such form as to eliminate angles, as at 6. The terminal 7 of the compound screw structure is of conoidal formation, as distinguished from the more common pointed terminal.

In driving the compound screw, illustrated by the Figure 1, into unbored wooden material, or the like, the conoidal terminal 7 is first placed upon the surface of the material and then driven therein by means of hammer blows, or the like, until the thread 5 begins to enter the wood. Then, by turning the compound screw by means of a screw-driver or the like, the lower threaded section 4 enters the depression made by the terminal and, further compressing the material therein, marginally forms its own threaded course so that, when the section 4 has entirely entered the material, the continued turning of the compound screw causes the threaded section 4 to gradually draw the threaded section 2 within the material to further marginally depress and to form its threaded course of increased diameter therein. The advantage of having the section 4 first enter the material is at least two-fold: The section 4 is of course easier to enter the material, it being of lesser diameter than that of the section 2, and, having fully entered, draws the section 2 therein after it, and the lateral strain upon the material which would have occurred had the section 2 first been introduced is avoided by means of the compound structure.

In the Figure 2 there are shown the head 1', upper section 2', upper section thread 5', the periphery 6' and the conoidal terminal 7', the thread 3' however terminates with the cutting shoulder 8. In driving this compound screw into unbored material, the operation is similar to that of the Figure 1, excepting that the threaded section 4' having entered the material will, upon further turning of the compound screw therein, draw the cutting shoulder 8 of the thread 3' of the section 2' of the greater diameter into contact with the material to marginally cut its enlarged threaded course therein, thereby further depressing the material as in the Figure 1.

In the Figure 3, as in the previous figure, there are illustrated the head 1'', upper section 2'', upper section thread 3'', the lower section 4'', the periphery 6'', the conoidal terminal 7'' and the cutting shoulder 8' of the thread 3'', the lower section 4'' of less diameter than that of the section 2'' being shown as unthreaded. In driving this compound screw into unbored material, the operation is similar to that of the previous figures, excepting that sufficient hammer blows, or the like, are necessary to drive the lower section 4'' entirely into the material until the cutting shoulder 8' of the threaded section 2'' of greater diameter is drawn into the material wherein it may marginally cut its enlarged threaded course therein upon the turning of the compound screw.

In the Figure 4, there is illustrated a compound screw in which the component integral sections combine the head 1''', the uppermost shank section 2''' having the thread 3''' with the inter-

mediate section 4''' having the thread 5''', the periphery 6''' connecting the sections 2''' and 4''', and the unthreaded section 9, the periphery 10 connecting the sections 4''' and 9, the compound screw terminating with the conoidal formation 7'''. In driving this form of compound screw into unbored material, the operation is similar to that of the Figure 3, with the exception that hammer blows, or the like, will have driven the unthreaded section 9 into the material before the threaded intermediate section 4''' can be turned into the material to be followed by the threaded section 2''' which finally is turned therein. This last described form of compound screw is well adapted for easy driving into material where a longer compound screw of greater section diameters may be used to advantage.

While the threaded sections are above described as having, in each instance, similar convolutions of uniform number to the inch, it is to be understood that such number may be varied with reference to sections of the same compound screw. Also, while the threaded sections are shown as having single convolutions of thread, they may just as well be provided with multiple convolutions, if desired. It is further understood that the invention herein disclosed is not to be confined to the illustrations shown, they being merely illustrative of different embodiments of the invention, and other combinations of compound screw sections, within the spirit of the invention, are intended to be included herein.

I claim:

A compound screw adapted to be driven into nonbored wooden material, or the like, the screw comprising a headed cylindrical shank section threaded from adjacent said head throughout its length; one or more other cylindrical shank sections, each of less diameter than that of the headed and preceding section, certain of said other sections being threaded throughout and the convolutions of all threaded sections being of the same number to the inch; nonthreaded tapered sections integrally connecting the cylindrical sections; a substantially abrupt cutting shoulder with which each terminal of the threaded sections is provided; and a conoidal terminal provided by the screw.

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United States Patent [19]

Vrespa

[11] Patent Number: 5,259,398

[45] Date of Patent: Nov. 9, 1993

[54] METHOD FOR FIXING PROSTHESIS TO BONES

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[21] Appl. No.: 601,416

[22] Filed: Oct. 22, 1990

[30] Foreign Application Priority Data

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[51] Int. Cl.[5] A61B 19/00; A61F 5/04; A61F 2/28

[52] U.S. Cl. 128/898; 606/65; 606/67; 606/73; 606/104; 606/80; 623/16

[58] Field of Search 606/80, 96, 104, 72, 606/73, 79, 65, 67, 68; 128/898; 623/16

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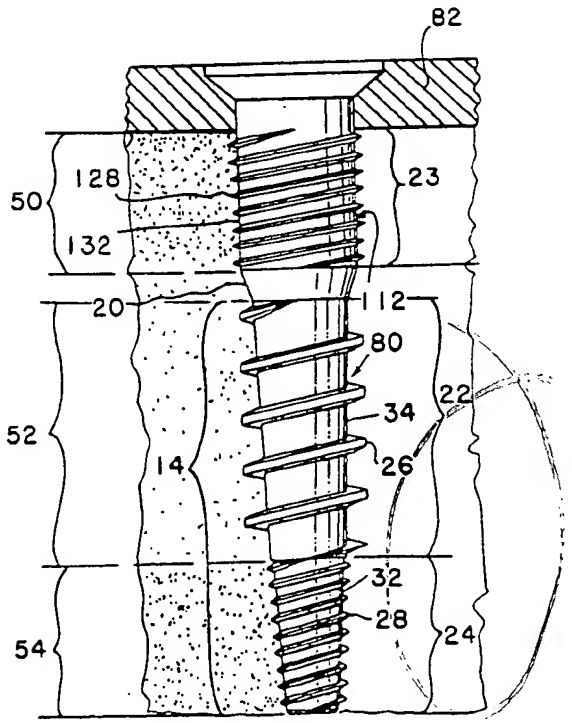
Primary Examiner—David Isabella
Assistant Examiner—Elizabeth M. Burke
Attorney, Agent, or Firm—Ladas & Parry

[57] ABSTRACT

In a screw device (10; 80) for fixing prostheses to bones, the threaded shank (14) comprises a core (32, 34) of overall frusto-conical shape. The screw has a cylindrical neck (12) of diameter equal to or greater than the maximum diameter of the thread. This latter is of two different types, namely a first thread (26) of large pitch for fixing into the trabecular bone tissue (52) and a second thread (28), which can be of the self-tapping type, for fixing into the cortical bone opposite the point at which the screw is inserted into the bone. The second thread (28) has a number of starts which is a multiple of that of the first thread (26). For orthopedic use the screw (80) can comprise a third thread (128) on a part of the neck (112) for fixing into the relative cortical bone (50). A method for applying the screw device (10; 80) consists of forming a precision hole (40) in the bone, tapping said hole with a tapper (60; 100), and screwing the screw (10; 80) into it. The precision hole (40) is obtained by using a cutter (100) in the shape of an inverted "wedding cake", then reaming the obtained cavity with a manual reamer (140).

14 Claims, 4 Drawing Sheets



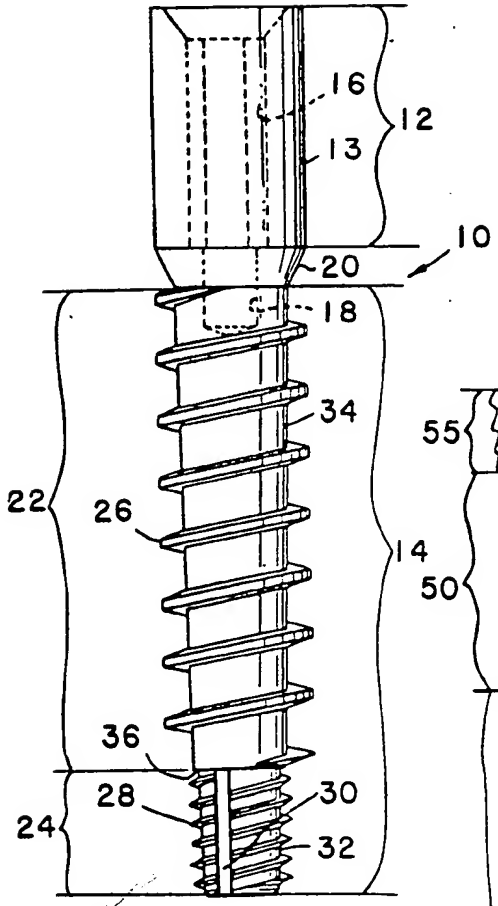

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FIG.1

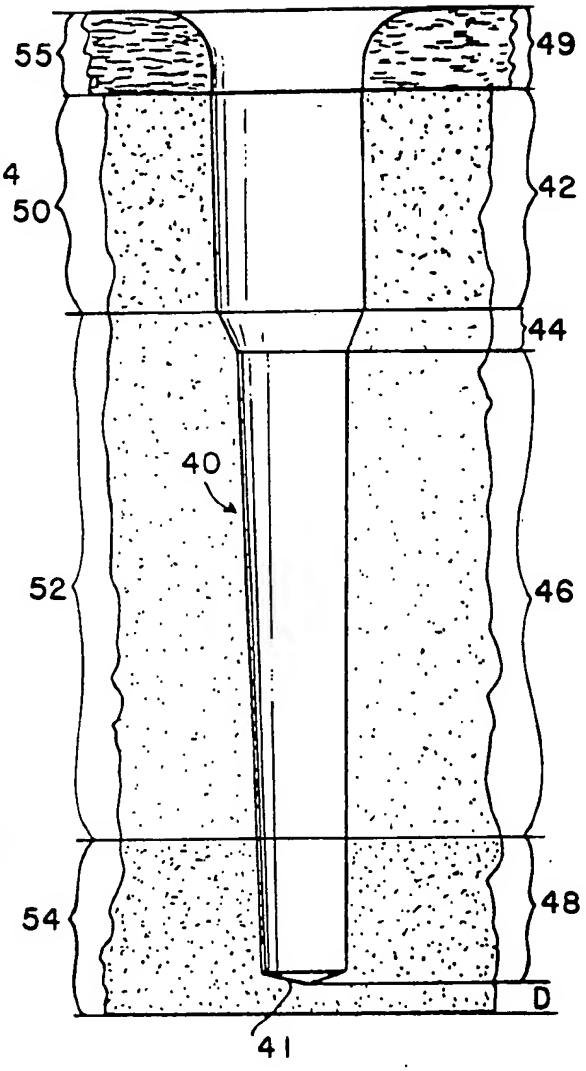
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FIG.2

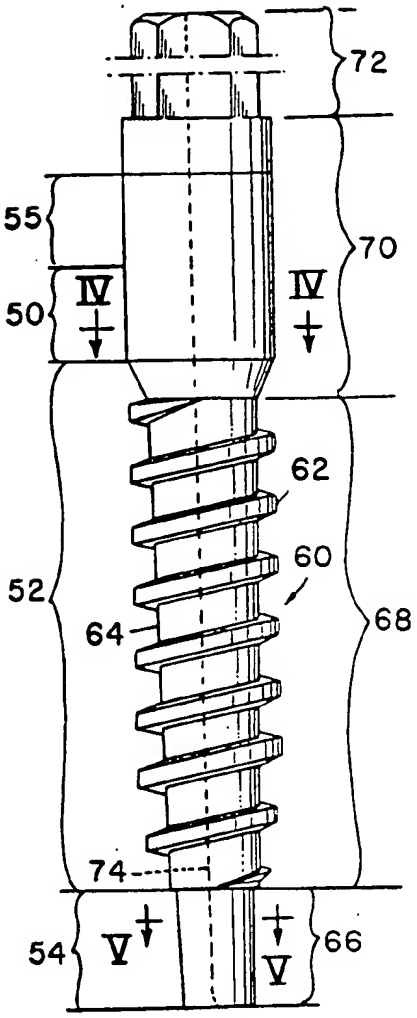


FIG.3

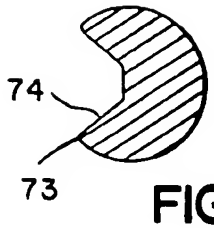


FIG.4

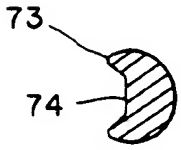


FIG.5

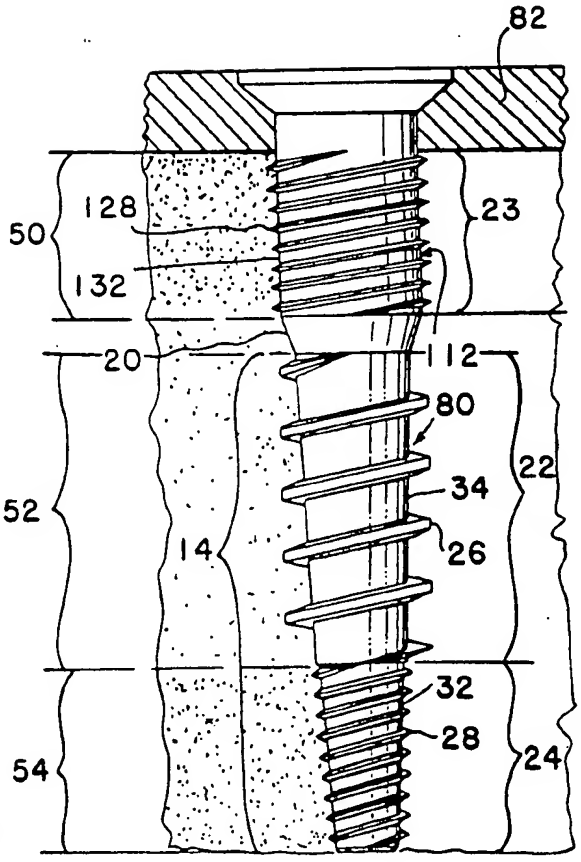


FIG.8

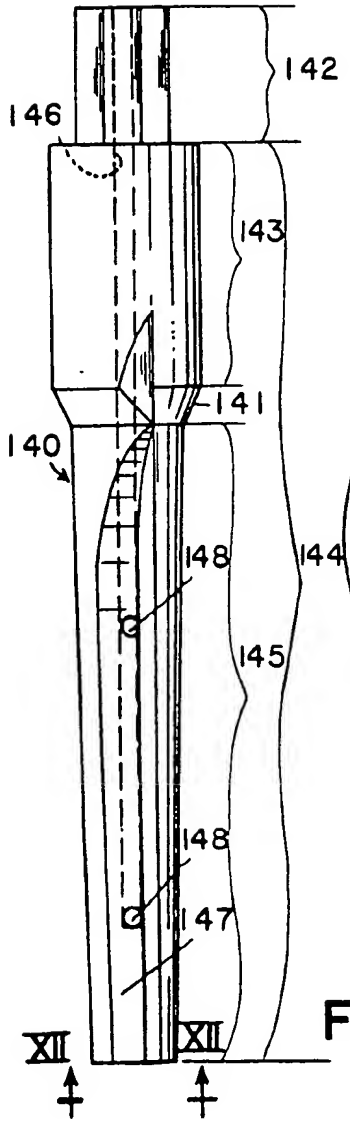


FIG.11

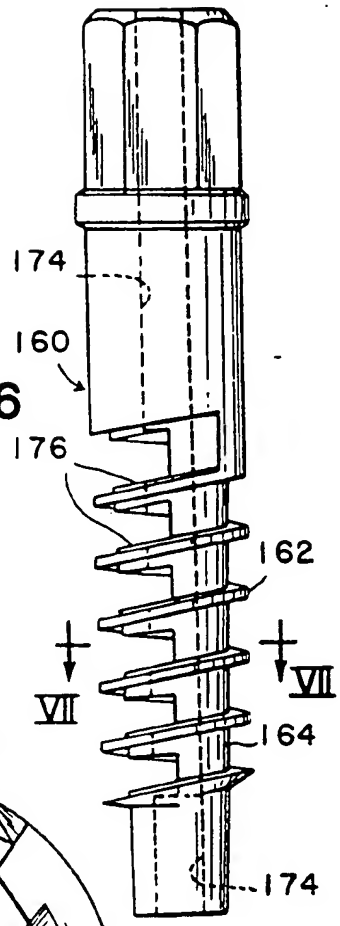


FIG.6

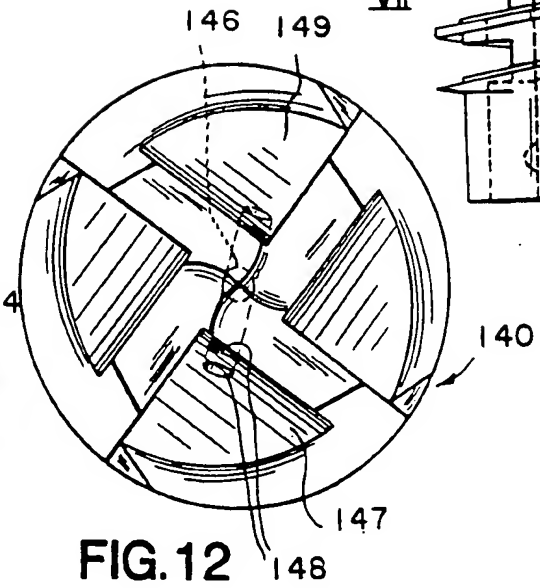
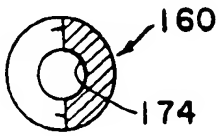
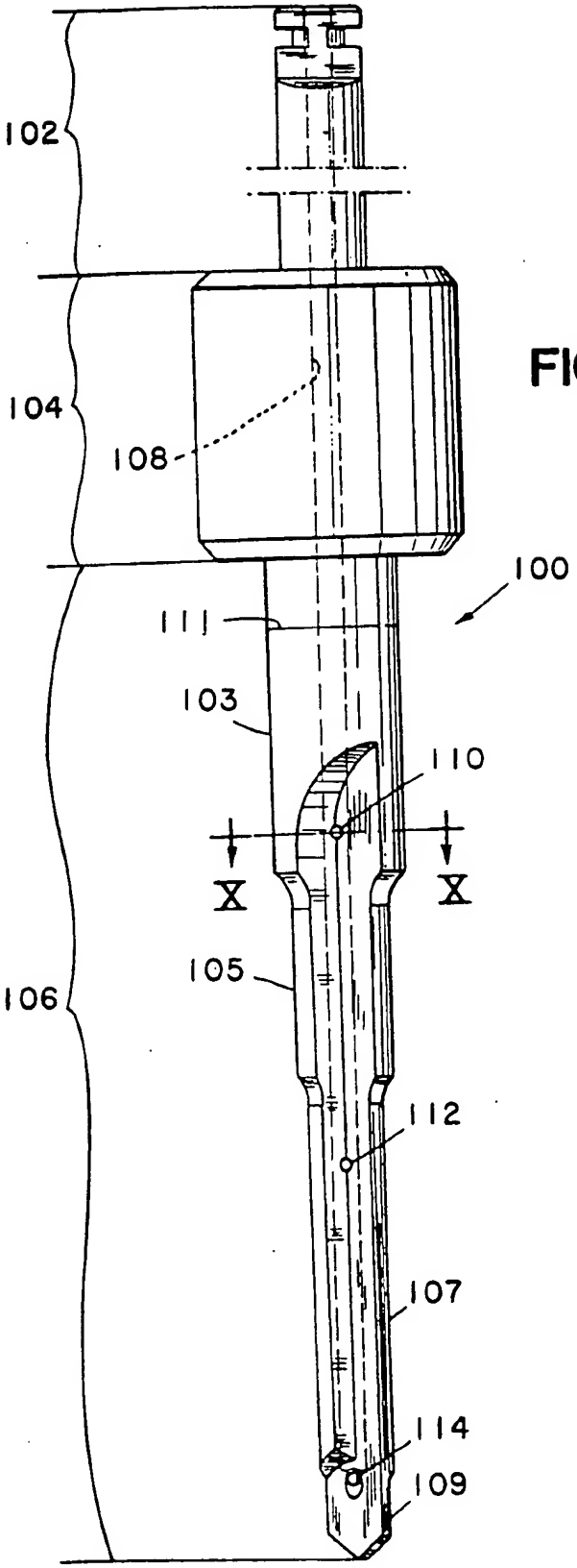


FIG.12

FIG.7

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108
100
111
103
110
X
X
105
106
112
107
114
109

FIG.9

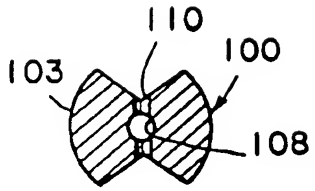

110
100
103
108

FIG.10

METHOD FOR FIXING PROSTHESIS TO BONES

DESCRIPTION

This invention relates to means for fixing prostheses to bones, and more specifically to screw devices for effecting this fixing. The invention also relates to a method for applying said screw device and the relative instrument for the application.

As is well known, in terms of mechanical characteristics bone tissue can be divided into two distinct regions, namely the cortical bone region with an elastic modulus of between 1000 and 1200 dN/mm^2 and the spongy region, of trabecular bone tissue containing medulla or fat, with an elastic modulus of roughly between 20 and 400 dN/mm^2.

Currently, to execute an implant in any bone, use is made of known bone screws which have a substantially cylindrical shank and are constructed of a biocompatible metal such as titanium, austenitic stainless steel, tantalum, niobium or zirconium. These screws require a cylindrical hole to be previously drilled in the bone. If the screws are of the self-tapping type they are inserted directly into the cavity thus obtained, which always has a diameter less or at most equal to the core of the screw. In the case of non self-tapping screws the relative female thread has to be formed in the side surface of the hole.

For fixing purposes, known screws utilize either the mechanical characteristics of the trabecula and therefore have a thread of rather large pitch, of the type suitable for fairly soft materials, or the mechanical characteristics of the cortical bone opposite the point of penetration of the screw, which has a thread pitch significantly less than in the previous case and suitable for ensuring a good mechanical grip in hard materials, but not suitable for gripping the trabecular bone tissue.

In its turn, because of its thinness the cotical region of the bone can generally only receive one large-pitch turn. In addition, because of its relative fragility the cortical bone tissue is unsuitable for receiving a large-pitch thread.

This applies particularly to the cortical bone located on the same side as that from which the self-tapping screw or thread tapper is inserted. In this respect, as stated the thread of the screw or tapper has a diameter greater than that of the drilled hole. In addition the screw neck (i.e. the cylindrical end of the screw to which the prosthesis is fixed, and which is normally not threaded but enters the cortical bone) has a diameter less than that of the thread. As a result, on inserting the self-tapping screw or tapper into the drilled hole the most outer part, i.e. the cortical bone, of the bone tissue is removed. Consequently, once the screw has been inserted into the bone, an empty annular space remains around the screw neck. This means that the cortical bone is surgically damaged for a certain area around the screw neck. The damage is directly proportional to the size of the tooth of the thread on the self-tapping screw or tapper. That part of the cortical bone which has been thus removed does not form again. This represents a serious drawback as the cortical bone is the strongest region of the bone and the most suitable for supporting loads, particularly loads perpendicular to the screw axis. The cavity for receiving the screw is formed by rotary tools mounted on hand-controlled drills.

The shape and dimensions of the cavity obtained depend on various factors, and in particular:

a) the bone to be drilled;

b) the drilling tool;

c) the operator holding the drilling tool.

The causes influencing these three factors will be examined in detail:

a) The bone to be drilled cannot be fixed rigidly, with the result that there is a certain freedom of movement. It also has a smooth, moist and therefore slippery surface. In addition the surface is somewhat round. Again, the structure is anisotropic so that the resistance offered to the tool cutting edge varies as drilling proceeds.

b) The drilling system comprises a drill bit or cutter of various shapes, such as a spade tip with a solid cylindrical body, a flared tip with a vertically grooved body to collect shavings, or a flared tip with a helically grooved body to collect shavings. No studies appear to have been carried out with the purpose of determining the best cutting angle for the bone, or conceiving a good system for discharging the bone shavings which mix with the blood and tend to coagulate. As is well known, when the drill bit is fitted into the drill it is retained by a quick-action mechanism consisting of a hollow neck which receives the relative part of the bit, which is thus locked in terms of axial movement, whereas the bit has a certain radial play. Consequently the bit does not rotate about a fixed axis but about an axis which can undergo small oscillations and movements perpendicular to itself. The mechanism which transmits movement to the drill bit can also move slightly because of intrinsic mechanical play within the mechanism. The combination of all these causes means that the drill bit undergoes a complex "wobbling" movement.

c) The hand of the operator gripping the drill is subject to muscular control, which varies from operator to operator and can also vary with time for the same operator.

From the aforegoing, and considering any cross-section through a drill bit when freely rotating, before it makes contact with the bone it describes a peripheral or enveloping circle which has a diameter greater than the true diameter of the bit at that cross-section, because of the effect of said wobbling.

Moreover when the tip of the drill bit comes into contact with the bone, no matter how expert or attentive the operator is, the bit axis is generally not exactly perpendicular to the bone surface. Consequently, even if a starter cavity is present (previously made in the bone surface), when the operator exerts a certain pressure on the bit to drill the hole, a non-axial reaction is applied to the bit, which consists of one component perpendicular to the bit axis to flex it, and a second component along the bit axis. Said flexing force has two effects, the first being the nullifying of the radial play of the mechanism which holds the bit so that said peripheral circle becomes the maximum possible, the second effect arising when play has been nullified, to deform the bit by flexure, so further increasing the diameter of the peripheral circle.

When the drill bit has initially entered the bone a cavity of previously indeterminable diameter results, this diameter being in any event certainly greater than that of the corresponding cross-section of the bit. This

cavity will have a certain depth, say one or two millimeters.

It is therefore apparent that the amount of play varies in practice and cannot be controlled, and it can only be stated that the drill bit will advance through this first section in a merely "prevalent" direction, being substantially that of the theoretical axis of the bit. It is however apparent from the aforegoing that the inaccuracy will be somewhat high.

In practice, in its initial portion the cavity can be considered to consist of a series of probably irregular superposed circles of variable diameter, slightly mutually off-centre, to form a cavity extending prevalently in a certain direction.

When further pressure is applied to the drill bit it advances through the bone. Two new substantial factors now come into play to influence the operation, namely the accumulation of shavings which tend to coagulate, and the presence of the part of the cavity which has already been drilled.

The presence of shavings increases friction, to generate heat and result in further small removals of bone material from the cavity walls. The friction can increase to the extent of stopping the drill motor.

The shavings must therefore be removed whatever type of drill bit is used. This is firstly to prevent the bit heating, and secondly to allow it to move forward. They are removed by extracting the bit from the hole. Each time this is done new material is inevitably removed from the walls of the already drilled hole. That part of the hole which has already been drilled performs the important function of guiding the cylindrical body of the bit. In bits with a helical groove this body has a cutting or partly cutting effect, whereas in bits without a groove or with a vertical groove it does not cut.

If the bit body has a cutting or partly cutting effect each change in the bit direction results in a removal of material. The cavity therefore widens, so reducing its guide function. As stated, on termination of the operation the cavity is found to be formed from a series of superimposed circles of a diameter which varies within a certain range and slightly off centre to each other, to form a cavity which is therefore somewhat irregular. Of necessity the cavity will have a diameter which is greatest at its open end and smallest at its other end.

If the bit body does not have a cutting effect, the guiding efficiency of the already drilled cavity increases with increasing depth. However this does not mean that greater accuracy is obtained in drilling the cavity. In fact all the reasons which make the initial cavity wider than required (from the wobbling of the drill bit to the non-perpendicularity between the bit and the surface of the bone) remain. In fact, a further drawback arises, and one which helically bodied bits do not possess, namely that drill bits with a cylindrical lateral surface do not have space for discharging the shavings. The bit must therefore be extracted much more frequently to clean it, this finally resulting in further widening of the cavity. The bit penetration movement is in reality helical in the direction of rotation of the drill, this movement being a combination of advancement and rotation. Thus on termination of an in-vivo bone drilling operation conducted by normal surgical methods, the result is an approximately frusto-conical cavity of unknown diameters but certainly greater than the diameters of the drill bit used.

From tests carried out it has been found that this increase is in the order of some tenths of a millimeter, with wide variation. To make an initial approximate guess at the type of cavity obtained, one must think of a pile of discs with diameters gradually increasing upwards and decreasing towards the lower end. The discs will be slightly off-centre to each other and their centres will approximately form an irregular helical pattern. If an ideal axis is imagined passing through the centres of the two end discs, the centres of the intermediate discs will not generally lie on this axis but will lie within a certain helix about it.

If a circle is drawn having the nominal diameter of the screw (having an overall cylindrical shape) and centered on said axis, and then on this circle a further circle is drawn having the measured diameter of a certain cross-section of the cavity obtained and with its centre in its true position eccentric to the axis, the points of contact, if there are any, and the maximum distances between the two circles can be seen. If this operation is repeated for a certain number of cross-sections the number of points of contact between the screw and cavity can be determined accurately, as can the size of the non-adhering regions and their distance from the screw. This also clarifies why even with an effective diameter which is constantly greater than the nominal diameter of the drill bit there can only be a number of points of contact distributed randomly over the surface of the cavity. If in order to verify this a drill bit is inserted into the cavity obtained, the bit may appear stable if by chance it touches the walls at a few points, but these do not ensure effective stability. What however normally happens is that the drill bit has a certain play when inserted into the cavity, showing that there is an insufficient number of points of contact.

Consequently when the cavity is finally tapped, the resultant thread will be complete in terms of depth only at the said points of contact, whereas the remainder of the thread will be only partial or indeed be completely lacking.

This however does not mean that sufficient information is available to ensure healing, given that it is not known how and in particular when the bone will reform.

The question arises as to whether it is possible to adapt operational technology in such a manner as to obtain cavities with a precision of the order of that obtainable in the machining of the actual implants to be inserted into the cavity. The present invention shows that this is possible. In this respect it teaches that such levels of precision can be in reality obtained without having to use too complicated and very costly procedures. In this respect, with the present invention precision levels of 0.02 mm as general dimensional tolerance can be obtained, while for a series of reasons which have already been stated a precision of 0.01 mm can be obtained for surface irregularities, which can be considered optimal.

The reason for this search for precision is to reduce as much as possible, and in the theoretical limit to zero, the quantity of bone tissue which has to reform about the implant.

The problem of play between the drill bit and chuck and the intrinsic play within the drill head can only be solved by completely changing current technology. This however would result in very high cost.

It has been seen that any movement of the screw relative to the walls of the cavity which receives it has a negative effect on the repair of the bone lesion.

The object must therefore be to obtain a connection in which such relative movement is not possible. This need is currently satisfied by using a more or less forced insertion of the implant into the cavity. The bone tissue in contact with the implant is therefore compressed. This compression is the price paid by all known insertion methods which provide initial immobility of the implant. The blades or cylinders currently used for this purpose are in fact inserted with small hammer blows. In this manner a forced fit is obtained between the bone and implant by virtue of the mutual compression between certain regions of the implant and the corresponding regions of the cellular wall.

Implants formed from different elements (disk implants) utilize the traction between screw elements and prismatic bodies to obtain bone-implant adhesion areas which provide the necessary initial stability.

The screw has encountered considerable success because it enables an excellent and immediate rigid connection to be easily obtained between the implant and bone. This method has however certain negative aspects due to two basic reasons, namely the trauma (COMPRESSION) produced by the helical thread in the tissue, and the transmission to the bone, via the thread, of loads perpendicular to the screw axis.

Attempts have been made to solve both these problems by eliminating the thread and proposing cylindrically shaped implants, but these demonstrate poor initial stability (PRIMARY), require larger holes to be made, require higher bone crests and provide a lesser lateral surface for equal dimensions. In reality the solution to the problem does not consist of attaining a stability which allows any level of bone repair, but consists of establishing best bone conditions for healing.

The best healing conditions are obtained by satisfying two general conditions:

1. Reducing surgical trauma to a minimum and eliminating debris.
2. Attaining maximum initial congruence with minimum pressure.

These two conditions result in an improvement in the progress of the reparative process, which normally involves:

1) Resorption of certain bone tissue;
2) Reshaping of other bone tissue;
3) Bone tissue neoformation.

The reduction in surgical trauma limits the necrosis of the tissue of the cellular implant wall; the elimination of debris avoids compression, resorption and infection. The fact of obtaining maximum congruence with minimum pressure results in primary stability, no bone resorption stage, no bone to be neoformed in the cortical bone part and little in the spongy part. The female thread is currently made in the bone by two substantially different methods, namely by partial mechanical tapping (as in the Branemark method), and by self-tapping screws (as in the case of Tramonte screws).

Partial mechanical tapping involves the insertion of self-tapping screws which traumatize the bone and retain all the debris. This means that with Branemark screws the bone in contact is quickly resorbed and congruence is lost. The reparative process takes place by callus formation.

Self-tapping screws of Tramonte type allow maximum congruence between the thread and bone, but involve a forced compressive insertion which causes serious damage.

The insertion of either a self-tapping screw or a tapper into the drilled cavity causes both local and general effects in the bone, as follows:

I—Local effects

These are caused by the following actions:

a) Cutting action

The cutting action of the thread separates the bone tissue, damaging the calcified bone matrix, the collagen, the basic substance, the cells, the vessels and the nerves. At the commencement of the tapping operation and in the case of the self-tapping screw the cutting action causes inflammation and loss of blood. The tissue lesion results in the release of inflammatory substances (H. W. HAM—Istologia, USES 1969).

b) Compression action at interface

As the tapping or the insertion of the self-tapping screw continues, the tissue is divaricated by the thread. On commencement of tapping or insertion of the self-tapping screw, if there is no counteracting element in contact with the bone surface breakage occurs by raising of the cortical bone surface, with consequent disruption of the architecture in the surrounding region. In particular, it is the tearing of the vascular connections which seriously prejudice the bone reparative process in this region. In the compagination of the tissue, the divarication necessary for the advancing movement of the thread is obtained by compression of the tissue at the interface. Under the advancement thrust the bone tissue volume corresponding to the volume of the tapper thread or of the thread of the self-tapping screw is fractured and pushed to the sides of the advancing thread. As the spongy trabecular bone tissue lies below the cortical bone, its disturbed solid part, formed of calcium salts, fills the entire available surrounding space, squeezing the vessels contained in the medulla and reducing the blood flow, with consequent ischemia, whereas its liquid part is thrust into the most peripheral trabecular region.

If the thread has a pitch which results in superposing in the spongy bone tissue regions, which then become compressed by two successive turns of the thread, a particularly negative situation arises due to the combining of harmful effects which complicate healing. In determining the pitch of the thread of self-tapping screws or of the tapper, the size of the relative core and the size of the cavity to drill in the bone, this important aspect must be taken into account.

c) Action of heat

It is well known that the heat developed in the bone during the drilling of the hole into which the self-tapping screw or tapper is to be inserted is the main cause of formation of cicatricial fibrous connective tissue, rather than new bone tissue, in the subsequent reparative process which the surgical lesion undergoes. For this reason, in drilling said hole it is advisable to use known rotary instruments internally cooled by physiological solution which in addition to cooling the drill bit also removes the bone shavings by collecting them in the grooves provided. Another method for reducing the heat produced is to limit the rotational speed of the drill to the minimum rpm which allows the hole to be drilled.

Likewise the tapping operation or the insertion of the self-tapping screw must also be very slow, so that all phenomena arising can be considered of static type, and the applied forces must be only just greater than equilibrium forces. It is essential to limit friction so as not to excessively increase temperature, which in practice

must be maintained below 44° C. The rate of tapping or of insertion of the self-tapping screw must therefore be the lowest possible for screwing into the bone. This operation can therefore only be carried out manually. The use of motorized tappers or screwdrivers does not allow easy control of the speed or consequently of heat produced. In conclusion, in the current state of the art, as a result of a combination of the aforesaid local effects, the damaged spongy bone tissue becomes replaced with soft cicatricial tissue, which by its nature is unable to ensure effective fixing to the screw.

II—General effects

As is well known, the trabecular spaces are not empty, nor is any part of the bone. The system which they form can be considered a closed hydraulic system containing a system of channels through which blood flows. Consequently the insertion of an additional volume must necessarily result in a reduction in the blood flow and an increase in the total volume of the system. Thus as in the known art the drilled hole is equal at most to the volume of the screw core, inserting the self-tapping screw or the tapper means that an additional volume is inserted into the bone tissue which is at least equal to the volume of the threads. This produces a significant increase in the internal pressure of the bone, which can easily exceed the breakage limit of the bone and cause fracture. Such fracture does not generally occur at the interface, where the aforesaid local phenomena occur, but starts from the external cortical bone, at the hole. Any excessive increase in the pressure within the system must therefore be avoided.

There is a second effect which produces a pressure increase within the bone. This is generated by the insertion of a self-tapping screw of a tapper of known type. This is because from the very commencement of their insertion these close the hole in the bone, from which the blood should emerge. This blood is therefore pushed to the base of the hole to further increase the internal pressure of the bone, so that said fracture risk increases. The object of the present invention is to overcome the aforesaid drawbacks of known bone screws and of their methods of application, by providing a screw device for fixing prostheses to bones, a method for applying the device, and the instrument for effecting the application, such as to result in spontaneous repair (by creeping substitution) of the lamellar bone tissue around the screw, the screw becoming thus securely and permanently fixed in the bone. To obtain healing by creeping substitution, a method of bone repair essentially identical to bone rearrangement, the quantity of blood coagulum present at the surface of the screw implant according to the present invention must be minimal. This is because blood coagulum converts into mature lamellar bone very slowly (6–12 months in man), by a self-limiting process. This latter characteristic means that ossification of the coagulum may not go to completion, and instead give rise to the formation of fibrous tissue unsuitable for supporting loads.

To enable creeping substitution to take place it is also essential that the vascular channels in the necrotic lamellar bone are not destroyed, and thus the pressure exerted during screwing must be a minimum.

The present invention proposes firstly to substantially eliminate the blood coagulum between the calcified bone and the implant by obtaining the maximum possible congruence or adhesion between the bone tissue and the relative parts of the screw, without any pressure being exerted which could irreparably damage the lamellar bone.

In particular, it is essential that the cavity formed in the bone has a degree of precision substantially higher than that currently obtainable in the known art, so as to reduce to a minimum the amount of bone tissue which has to reform. The screw must also have a shape which reduces the amount of bone tissue to be reformed to a minimum.

During healing, in order for the necrotic lamellar bone tissue transformation to take place by creeping substitution (which preserves the special mechanical characteristics of lamellar bone and takes place within 6–12 weeks), it is essential to prevent the aforesaid phenomena occuring. In particular any resorption of marginal bone or bone debris must be prevented. This ensures primary stability, which is essential. In this case, even during the healing period, during which for obvious reasons one tries not to load the screw, this latter is able to support those small loads which accidentally but almost inevitably tend to act on it, without any negative consequences arising.

The screw device according to the present invention comprises a neck and a threaded shank, and is characterised in that the threaded shank of the screw has a core of overall frusto-conical shape, the screw core being cylindrical and having a diameter equal to or just greater than the maximum diameter of the thread on the shank of the screw, and the thread being of two different types, namely a first thread of large pitch suitable for fixing into the trabecular bone tissue and extending along that part of the shank which is designed to make contact with said trabecular tissue, and a second thread, which can be of the self-tapping type, and intended to fix into that cortical part of the bone opposite the part into which the screw is inserted, said second thread having a number of starts which is a multiple of that of the first thread.

In contrast to a screw with a cylindrical core, a screw with a frusto-conical core, because of its particular geometrical shape and if associated with a corresponding suitable frusto-conical cavity of adequate precision, reduces the quantity of bone tissue to be reformed practically to zero, with maximum congruence obtained between the screw and cavity.

In addition, because of the double type of thread, the described screw can fix effectively into both the trabecular bone tissue and into the cortical bone.

The fact that the screw neck, which when the screw is inserted lies only in the cortical bone on the screw insertion side, has a diameter greater or in the limit equal to that of the thread, means that the hole made in the bone must have a first portion, in practice equal only to said cortical bone, having a diameter at least equal to the neck diameter. Thus on inserting the self-tapping screw or tapper the cortical bone is not ruined. If a fixing means or the like is present in contact with that cortical bone surface at which the screw is inserted to act as a counteracting means (for example in the case of screws for orthopedic use a prosthesis or a bone synthesis means resting against the surface), the screw according to the invention can comprise on the lateral surface of the screw neck a third thread of the same type as said second thread.

In this respect it has been found that the existence of said counteracting means in contact with the surfaces of said cortical bone prevents the lifting and destruction of the most outer part of the cortical bone, which could

happen when said third self-tapping thread penetrates into the cortical bone if such a counteracting means were absent. A situation of this type occurs for example when a plate has to be applied for the synthesis of bone fractures.

In the particular stated case a fixing is therefore also obtained at the cortical bone via the screw neck, to obtain the best possible fixing for the screw in the bone.

To obtain the best result from the use of the screw device according to the invention a particular method of application must be followed for the device. This method also forms part of the present invention and enables a cavity to be obtained having dimensions substantially more precise than that obtainable by the known art and such as to reduce the quantity of bone tissue to be reformed to a minimum.

Specifically, the method for applying the screw device of the invention consists of:

forming a precision hole in the bone in the position in which said screw device is to be inserted, the hole comprising: a first more outer cylindrical portion to receive the screw neck, this first portion having a diameter equal to or preferably slightly less than that of the non-threaded neck of the screw, or slightly greater than the maximum core diameter of the neck if this latter is threaded; a second more inner frusto-conical portion of transverse dimensions equal to or preferably slightly less than those of the core of the first screw shank part carrying said first type of large-pitch thread; and a third portion extending along the remaining length of the screw shank, this third portion being relative to said second type of screw thread and of transverse dimensions slightly greater than those of the core of that shank part with said second type of thread; tapping the said second portion of the hole to obtain in it a female thread suitable for receiving the said first screw thread; if said second screw thread is not of self-tapping type, tapping said third portion to obtain in it a female thread suitable for receiving said second screw thread; completely screwing said screw into the tapped hole.

This method of application results in maximum congruence between the screw and bone.

The said hole provided in the bone can also be a through hole if appropriate.

The present invention also relates to a cutter and reamer for forming said precision hole, and a precision boring method using said cutter and reamer.

Specifically, the cutter according to the invention is cooled by sterile liquid which also performs the function of removing the bone shavings which form, and is characterised by having its cutting part in the shape of an inverted "wedding cake". By this term, which immediately enables the shape of the cutter to be visualized, it is meant that the cutter consists of a number of coaxial cylindrical bodies rigid with each other, their diameter decreasing towards the tip of the cutter.

The manual reamer according to the invention is of such form and dimensions as to enable the final hole to be obtained with the required precision, ready for tapping, and is characterised by having a relief angle suitable for cutting bone tissue. Conveniently, the reamer comprises means for conveying isotonic liquids into the cavity formed in the bone, to facilitate the operation. The purpose of such liquids is to reduce bone necrosis.

The means for conveying nutrient liquids can simply consist of a coaxial channel passing through the entire reamer, in communication with a device for feeding isotonic liquids and with lateral apertures provided between the reamer cutting edges, to enable the isotonic liquid to make contact with the tissues concerned.

The method for forming said precision hole for the insertion of a screw device according to the present invention consists of: forming with the inverted "wedding cake" cutter a cavity with steps having diameters less than or at most equal to those of the required precision hole; then, by means of said reamer, manually reaming the thus formed stepped cavity to obtain the required precision hole ready for tapping.

It has been found that the best results are obtained when both the (unthreaded) neck of the screw and the core of the first shank part of the screw have diameters which are slightly greater by a few microns than those of the relative hole. In this case the screw slightly compresses as it is screwed in, but without causing the damage previously described under point I(b). In this manner maximum congruence is obtained between the screw neck and thread on the one hand, and the bone tissue on the other, to also produce minimum bone damage.

It has also been found advantageous to screw the screw slightly further in once it has reached its final position in the cavity. This provides maximum adherence between the screw frustum or core and the cavity.

To form the large-pitch female thread in the side walls of the second hole portion to receive the first type of screw thread, the tapper according to the invention is used, having a tapping thread with a maximum diameter not exceeding that of the screw neck, this tapping thread having the same number of starts and the same pitch as the first screw thread, and extending for the same length as said first screw thread, the end part of the tapper, of length substantially equal to that of the second screw thread, being free of tapping threads and having transverse dimensions not exceeding those of the corresponding third portion of the hole if said second screw thread is of the self-tapping type, whereas said end part of the tapper has a tapping thread with the same number of starts and the same pitch as the second screw thread if this second thread is not self-tapping; the tapper having at least one discharge means to allow escape of the organic liquids. In one embodiment of the tapper according to the present invention the discharge means can be a coaxial channel communicating with apertures which open between the tapper threads. In a modified embodiment of the tapper according to the invention the discharge means are one or more longitudinal lateral grooves extending along the entire length of the tapper to interrupt all of its threads and partly involve the core of the tapper. The outer edges of each groove are conveniently rounded to reduce damage to the bone tissue to a minimum.

Preferably the directrices forming the frusto-conical core of the second screw thread are parallel, but internal, to the directrices forming the core of the first thread, so that a small annular step is present between the two surfaces.

When the screw has been inserted there is therefore an annular space between the core of the second thread and the corresponding side wall of the hole. This space acts as a compensation space which is at least partly filled by cortical bone bone tissue which is plastically deformed following introduction of the screw into the third hole portion if the screw if the second thread is self-tapping, or of the threaded end part of the tapper if the second screw thread is not self-tapping.

This compensates that thread volume which penetrates into the cortical bone, so that no dangerous pressure increase is created in the bone.

In the relative shank part of the second screw thread there can be provided at least one longitudinal groove having the double purpose of providing further compensation space for any other pressure increases which may arise, and of providing a region for collecting any bone shavings. Such pressure increases can be generated by fluid present under the tip of the screw, and which having no means of escape could undergo compression during screwing, with the stated consequent drawbacks.

Said vertical groove also acts as an anti-unscrewing device because new cortical bone tissue forms in it to prevent unscrewing.

- Thus in cases in which the screw is to be removed after a certain time period this groove must not be provided.

For the first type of screw thread an annular compensation space as provided for the second self-tapping thread is not essential, because of the different nature of the bone tissue concerned, i.e. trabecular. As stated, the tapper for forming the female thread for receiving the first screw thread cuts and laterally displaces the solid part of the spongy bone tissue, which fills the available adjacent space.

As also stated, the purpose of the discharge means provided in the tapper for the liquids contained in the bone is to enable both the blood emerging from the surgical would and that liquid fraction displaced by the formation of the female threads to escape. This enables local effects (which have already been mentioned) to be controlled to the desired degree and also inhibits the already mentioned negative general effects.

It has been stated that the discharge means can be grooves provided in the tapper. It should be noted that normal tappers for mechanical use also comprise longitudinal discharge grooves which interrupt the tapping threads and also involve their core. These grooves have however a different purpose. In these, the edges of the longitudinal grooves must be properly sharp in order to cut the material in which the female thread is to be formed. The purpose of these grooves is to allow collection and removal of the shavings formed by the action of the groove cutting edges against the hole wall.

In contrast in the present case, as the formation of shavings during the making of the large-pitch female thread is to be prevented and the said trabecular tissue compression is to be limited, the edges of the longitudinal groove are rounded. In tapping with the tapper according to the invention there is therefore no removal of bone tissue but only the removal of an equivalent volume of organic fluids. The trabecular tissue is therefore only cut and dislodged by the tapper threads without any pressure increase occurring. The spongy bone tissue therefore only undergoes displacement of the said solid and liquid, which does not prejudice the crawling substitution reparative process of the new lamellar bone tissue in the surrounding regions damaged by the tapping operation.

In penetrating the spongy bone tissue the large-pitch thread of the tapper must damage this tissue as little as possible. In particular, the crest of the first turn of the tapping thread must be pointed to allow optimum tissue cutting action. A convenient cross-sectional shape for the other turns of the tapper thread could therefore be trapezoidal without sharp edges, this being easily obtained mechanically. The first thread of the screw can also have threads of trapezoidal cross-section. This shape enables external loads perpendicular to the tapper axis to be absorbed without any cutting action occurring, and which would in contrast occur with pointed crests.

For the second screw thread involving the cortical bone, said problems are not so stringent, so that the cross-section of the relative thread can conveniently be triangular but with a rounded crest to avoid as much as possible any cutting action or dangerous load concentration should a force with a component perpendicular to the screw axis act on the screw.

The same applies to the tapping thread on the end of the tapper if the second screw thread is not self-tapping.

The invention will be more apparent from the following description of two embodiments of the screw according to the invention, of the hole for the screw, of the cutter and reamer for obtaining the required hole precision, and of the corresponding tapper.

Reference is made in this description to the accompanying drawings, in which:

FIG. 1 is a side view of a screw according to the invention, particularly suitable for odontology, of the type comprising a self-tapping second thread;

FIG. 2 is an axial longitudinal section through the hole for receiving the screw of FIG. 1, before the hole has been tapped;

FIG. 3 is a side view of a first embodiment of the tapper according to the invention for tapping the hole of FIG. 2, the tapper having an unthreaded end part;

FIG. 4 is a cross-section therethrough on the line IV—IV of FIG. 3;

FIG. 5 is a cross-section therethrough on the line V—V of FIG. 4;

FIG. 6 is a side view of a second embodiment of the tapper according to the invention;

FIG. 7 is a cross-section therethrough on the line VII—VII of FIG. 6;

FIG. 8 is a side view of a screw particularly suitable for orthopedics;

FIG. 9 is a side view of the inverted "wedding cake" cutter according to the present invention;

FIG. 10 is a cross-section therethrough on the line X—X of FIG. 9;

FIG. 11 is a side view of the reamer according to the present invention; and

FIG. 12 is an enlarged bottom view thereof on the line XII—XII of FIG. 11.

From FIG. 1 it can be seen that the screw 10 consists of two distinct basic parts, namely a cylindrical upper neck 12 and a threaded shank 14.

The threaded shank 14 is coaxial to the neck 12 and integral with it, and connects to the neck 12 via a short frusto-conical connecting section 20. This latter can however be absent, the frusto-conical surface of the screw core then extending directly from the periphery of the base of the cylindrical neck 12. The upper portion of the cylindrical neck 12 is intended to project beyond the bone, whereas the rest of the neck 12 is surrounded by the cortical bone with the screw inserted. A cylindrical rather than frusto-conical shape has been chosen for the screw neck 12, so that when under load the neck does not transmit axial loads to the adjacent cortical bone, but is able to transmit to the cortical bone any loads perpendicular to the axis of the screw 10 via its lateral surface 13 which is surrounded by it when the screw has been applied.

In the free upper surface of the cylindrical neck 12 there is an axial prismatic cavity 16 (shown by dashed lines in FIG. 1) to receive a suitable tool (Allen key or the like), not shown on the drawings, to enable the screw 10 to be manually screwed into the bone and to allow the screw to subsequently receive dental prostheses. These latter can for example comprise a pin-stump for prosthetic application by the method of Dr. Vrespa (Cenacolo Gruppo Italiano Studi Implantari, Bologna, November 187; Atti Congresso Internazionale GISI, May 1988). At the base of the prismatic cavity 16 there is a threaded or non-threaded axial hole 18 (shown dashed in FIG. 1), for fixing to the screw a known healing plug (not shown) or whatever else may be required. The presence of the two cavities 16 and 18 allows a mesostructure to be applied by screwing or cementing depending on the choice made and the requirements of the particular case. The shank 14 comprises two coaxially aligned parts 22 and 24 forming a single piece and having two different types of thread. Specifically, a first cylindrical single-start thread 26 of large pitch is provided on the upper part 22 of the shank 14. The first thread 26 is suitable for fixing into the spongy bone tissue, the relative thread having a trapezoidal cross-section with rounded edges. In the case shown in FIG. 1 the helical crest of the turns of the first thread 26 lie on a cylindrical surface having a diameter equal to the diameter of the screw neck 12, the outer diameter of the first thread thus being constant throughout its entire length. Consequently the height of the thread increases from the top downwards. In the case in which the frusto-conical connection 20 is not provided and if said surface is still cylindrical, the thread height starts from zero at its highest point.

Returning to the embodiment shown in FIG. 1, on the lower part 24 of the shank 14 there is a second thread 28 with three starts, each with the same pitch as the first thread 26. The second thread 28 is self-tapping. The thread turns are of triangular cross-section with a rounded crest. The thread height is constant along the entire thread. The thread crests lie on a frusto-conical surface parallel to that of the core 32 of the second thread. Because it has three starts this latter acts from the fixing viewpoint substantially as a thread having a pitch equal to $\frac{1}{3}$ of the effective pitch. This makes the thread suitable for fixing into the cortical bone, and in this specific case into the cortical bone opposite the point of introduction of the screw. The lengths of the various component parts of the screw are obviously such that when the screw is inserted into the bone the screw neck 12 lies mainly within the cortical bone on the side from which the screw is inserted, the intermediate part 22 of the shank 14 comprising the first thread 26 lies within the trabecular bone tissue, and the end part 24 of the shank 14 which contains the the second thread 28 lies mainly within the opposite cortical bone. In practice the screw neck 12 and the second thread 28 may lie slightly within the trabecular bone tissue region as it is difficult to previously know the exact thickness of the cortical bone.

As can be seen from FIG. 1, the part 24 of the shank 14 comprises a vertical groove 30 which interrupts the thread 28 and lies partly within the core 32.

The purpose of the groove 30, which can however also be absent, has already been stated.

From FIG. 1 it can be seen that both the core 34 of the upper part 22 of the shank 14 and the core 32 of the lower part 24 are frusto-conical (the relative lateral surfaces being parallel), but with a small step 36 between them.

The method of application of the screw of FIG. 1 and the tools for the purpose will now be briefly described, with particular reference to the making of the hole into which said screw is to be inserted.

The first operation consists of drilling in the bone a precision hole 40 shaped as in FIG. 2.

To do this the so-called inverted "wedding cake" cutters of the present invention are used. One of these cutters is shown in FIGS. 9 and 10. The cutter 100 consists of a shank 102 of conventional shape, a spacer portion or extension 104, and a cutter portion 106. The shank 102 is connected into the already mentioned quick-connection mechanism of the drill. The purpose of the extension 104, which is of suitable length, is merely to enable the cutter portion 106 to reach the required point, for example when a hole is to be drilled between two teeth adjacent to a missing tooth. If this requirement does not arise then the extension 104 can be absent.

As can be seen from FIGS. 9 and 10, the actual cutter part 106 consists substantially of three coaxial cutting bodies 103, 105 and 107, which are rigid with each other and arranged to produce three hole portions of circular cross-section and having a diameter which respectively decreases towards the interior of the bone.

The cutter 100 terminates with a tip 109 of conventional type and comprises an axial channel 108 communicating with the apertures 110, 112 and 114 visible in FIG. 9. The channel 108 enables the iosotonic cooling liquids to be discharged during bone drilling. Preferably a circular line 111 is engraved or otherwise reproduced on the cutting body 103 to visibly indicate the exact level to which the cutter 100 must penetrate into the bone. When the line 111 has reached the level of the bone surface it is therefore certain that the cutter has reached the required depth.

When a stepped hole of the stated type has been obtained in the bone by one advancement of the cutter 100, the hole is enlarged by means of a manual reamer of the present invention, to obtain a frusto-conical hole of the required precision (FIG. 2). A reamer of this type is shown in FIGS. 11 and 12.

As already stated, to obtain the desired results the reamer 140 must necessarily be operated manually.

The reamer 140 comprises a shank part 142 of hexagonal cross-section to be engaged by a suitable tool for the manual reaming of said stepped cavity, plus a reamer part 144, which has a relief angle suitable for cutting the bone tissue. The reamer part 144 is itself divided into two sections, namely a first section 143 for producing a cylindrical hole portion and a second section 145 for producing a frusto-conical hole portion.

In the specific case of FIG. 11, the first section 143 connects to the second section 145 via a frusto-conical connection 141. As stated, the reamer 140 also comprises an axial channel 146 which passes completely through it and communicates with lateral apertures 148 provided between the cutting edges. In the specific case of FIGS. 11 and 12 the lateral apertures 148 are four in number, two in the groove 147 and two in the opposite groove 149. The isotonic liquid is fed through the channel 146 to reduce bone necrosis.

When said reaming is complete a hole is obtained of the type shown in FIG. 2. This hole can also be a through hole or can stop at a certain distance D from the outer surface of the opposite cortical bone.

The first portion 42 of the hole 40 is cylindrical and has a diameter less by a few microns than the diameter of the cylindrical neck 12 (FIG. 1) of the screw. The height of this first portion 42 is equal to or slightly greater than the thickness of the cortical bone 50, and in any event sufficient for receiving that part of the neck 12 of the screw 10 which is intended to enter the bone.

The hole 40 proceeds inwards via a short frusto-conical connection portion 44, corresponding to the frusto-conical section 141 of the reamer 140 (FIG. 11) and to the frusto-conical portion of the screw 10 (FIG. 1). It connects the first section 42 to the second frusto-conical section 46. This latter has diameters less by a few microns than the diameters of the core 34 of the first part 22 of the shank 14 of the screw 10.

The hole 40 terminates with a third portion 48, which is nothing other than the prolongation into the opposite cortical bone 54 of the directrices of the second hole portion 46.

In the aforesaid case in which the screw 10 (FIG. 1) does not have the frusto-conical connection portion 20, the hole will also not have said connection portion 44, the second frusto-conical portion of the hole then extending directly from the base perimeter of the first cylindrical portion 42 of the hole. Likewise, the reamer 140 (FIG. 11) will also not have the frusto-conical connecting section 141.

Conveniently, the third portion 48 of the hole 40 is slightly longer (for example by 1 mm) than the corresponding lower part 24 of the shank 14 of the screw 10 (FIG. 1). The purpose of this is to prevent destruction of the female thread in the bone by any over-tightening of the screw, which could occur if the two said lengths are equal. In this respect any further advancement of the screw is prevented by the base 41 of the hole 40.

The slightly longer length of the hole 40 results in adhesion between the conical cavity and the core of the screw. This also compensates for tolerances.

In the specific case of dental screws, the upper cortical bone 50 becomes covered by the gingive 55 (see FIG. 2), so that this latter has to be perforated by conventional tools before proceeding with the drilling. The hole will therefore also comprise an upper gingival portion 49.

When the hole 40 has been made, a female thread (not shown in the figures) is formed in the side wall of its second portion 46 to receive the first thread 26 of the shank 14 of the screw 10. This is obtained using the tapper 60 shown in FIG. 3. To increase adhesion between the screw 10 and the new bone tissue which has to reform about the screw, the first part 22 of the shank 14 and the respective part of the neck 12 are normally coated with titanium in known manner by plasma spray treatment, which slightly increases its dimensions.

Consequently the dimensions of the tapping thread 62 and of the core 64 of the part 68 of the tapper 60 must be proportionally increased with respect to the dimensions of the bare screw, as must the dimensions of the parts 46, 42 and 44 of the hole 40. The lower frusto-conical part 66 of the tapper 60 is unthreaded, it has the same length as the corresponding second part 24 of the shank 14 of the screw 10, and at most has the same transverse dimensions as the core 32 of said part 24 of the screw.

The tapper also comprises an upper part 70 substantially analogous to the neck 12 of the screw 10, the part 70 upperly comprising a projection 72 having a polygonal cross-section for engagement by a suitable tool (not shown) to enable the tapper 60 to be inserted. This latter comprises a longitudinal groove 74 of substantially trapezoidal cross-section extending along the entire tapper (see also FIGS. 4 and 5), its purpose having already been stated. It will be noted that the edges 73 of the groove 74 are rounded, for the previously stated reasons.

FIGS. 6 and 7 show a modification of the tapper according to the invention which has proved particularly convenient. The tapper 160 is particularly suitable for tapping holes for receiving screws without the connection portion 20, so that the relative precision hole will be without the portion 44. The only true difference compared with the tapper 60 of FIGS. 3 to 5 is that instead of the longitudinal groove 74 (FIG. 3) for discharging the organic liquids there is a coaxial circular channel 174 which passes longitudinally through the entire tapper 160. This channel communicates with the outside not only at its two ends but also via the series of apertures 176 provided in the core part 164, each aperture opening between two successive turns of the tapping thread 162.

The dimensions of the tapper 160 of FIGS. 6 and 7 do not correspond to those of the screw of FIG. 1, as it relates to a shorter screw without the connection portion 20, as stated. When the hole 40 has been tapped, the screw 10 is screwed into it, its second self-tapping thread 24 penetrating securely into the opposite cortical bone 54 (FIG. 3).

After a suitable time period, required for crawling substitution in the cortical bone and the formation of primary bone in the spongy part, new bone tissue reforms in contact with the screw to ensure its stability with time.

FIG. 8 shows a modification of the screw according to the invention which is particularly suitable for orthopedics, for example for fixing a plate to a femur. The screw 80 is shown in FIG. 8 already inserted into the bone. It differs from the screw 10 of FIG. 1 only by the presence of a third self-tapping thread 23 provided on the lateral surface of the screw neck 112. The third thread 23 can be provided only if a counteracting element 82 is present, such as a plate resting on the surface of the femur cortical bone 50. The plate 82 prevents lifting and destruction of the surface layer of the cortical bone 50 when the self-tapping thread 23 grips the cortical bone 50.

The third thread 23 could also be not of self-tapping type. In this case, in the first portion 42 of the hole 40 a relative female thread is formed by a suitable tapper (not shown). The relative hole portion corresponding to the neck 112 of the screw 80 is consequently given a slightly larger diameter than the relative core 132 of the thread 23 of the screw 80, but less than the outer diameter of the thread 23, for the same reasons as stated for the hole corresponding to the second thread 28. As will be immediately apparent, the orthopedics screw 80 results in optimum stable fixing to the bone.

I claim:

1. A method for applying a screw device for fixing a prosthesis to bones, the screw device having a neck and a threaded shank, the shank having a core, a first thread portion of large pitch and a second thread portion, the method comprising:

forming a precision hole in the bone where the screw device is to be inserted, the hole comprising: a first outer cylindrical portion for receiving the neck, the first portion having a diameter equal to or

slightly less than the neck; a second inner frustoconical portion having a diameter equal to or slightly less than the core having the first thread portion; and a third portion having a diameter slightly greater than the core of the shank where the second thread portion is located;

tapping the second portion of the hole to form a female thread therein for receiving the first thread portion of the screw; and

completely screwing the screw device into the hole.

2. A method as claimed in claim 1 wherein the neck comprises a core and a thread thereabout, and the first portion of the hole has a diameter slightly greater than the core of the neck.

3. A method as claimed in claim 1 further comprising the step of tapping the third portion of the hole to obtain therein a female thread suitable for receiving the second thread portion.

4. A method as claimed in claim 1 wherein the second thread portion is self tapping.

5. A method as claimed in claim 1 wherein the hole is formed with a bone tissue cutter of the type cooled by sterile liquid, bone shavings are removed, and a telescoping shaped cutting part is provided.

6. A method as claimed in claim 1, further comprising the step of obtaining the hole with a reamer, the reamer having a relief angle suitable for cutting bone tissue, the method further comprising conveying isotonic liquids into a cavity formed in the bone.

7. A method as claimed in claim 6 wherein isotonic liquids are conveyed through a coaxial channel, the channel communicating with an isotonic feed device.

8. A method as claimed in claim 1 comprising first forming a stepped cavity having dimensions less than or equal to a required precision hole, and manually reaming the stepped cavity to obtain a hole of required precision.

9. A method as claimed in claim 1 further comprising forming a tapping thread in at least a portion of the precision hole, the tapping thread corresponding to thread on the screw device which will be located in the portion of the precision hole when the screw device is completely in the tapped hole.

10. A method as claimed in claim 1 comprising providing at least one longitudinal grooves to permit discharge of organic liquid.

11. A method as claimed in claim 1 wherein the third portion of the hole is slightly longer than the shank of the screw corresponding thereto.

12. A method as claimed in claim 1 wherein the first thread portion is substantially trapezoidal in cross-section, and the second thread portion is of substantially triangular cross-section.

13. A method as claimed in claim 1 wherein the first thread portion has a constant outer diameter.

14. A method as claimed in claim 1 further comprising locating a self-tapping thread on the neck of the screw device.

* * * * *

Aug. 28, 1962 GUSTAF-BERTIL L. GRATH 3,051,169

SURGICAL SCREW CONNECTOR

Filed Dec. 5, 1958

Fig.1

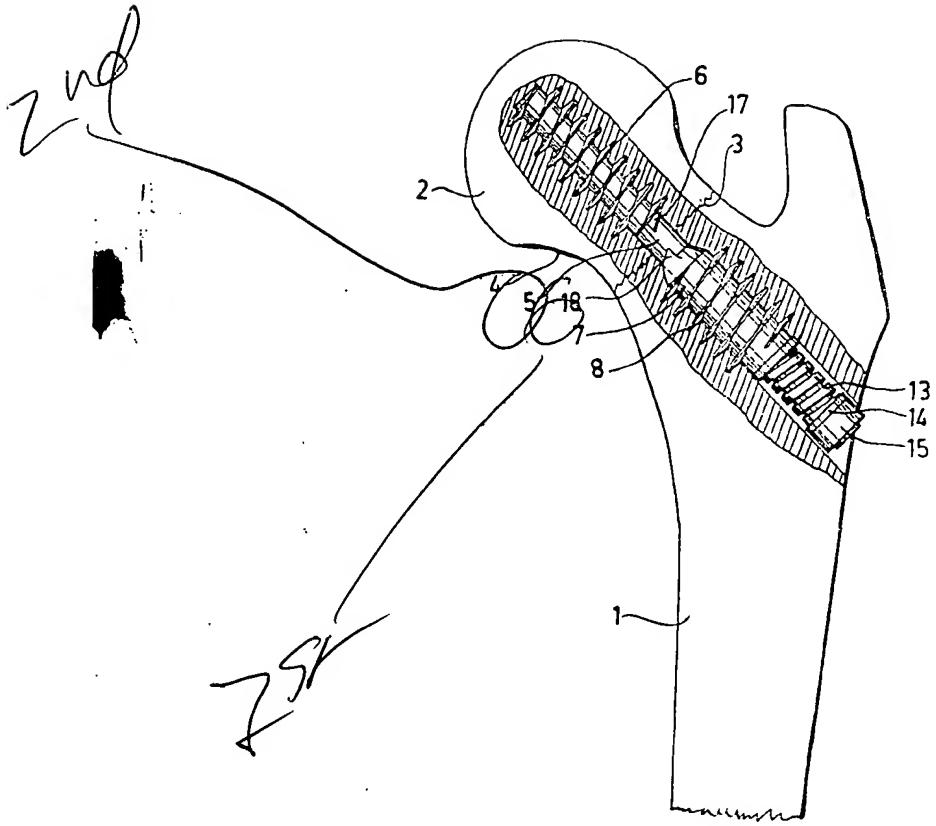
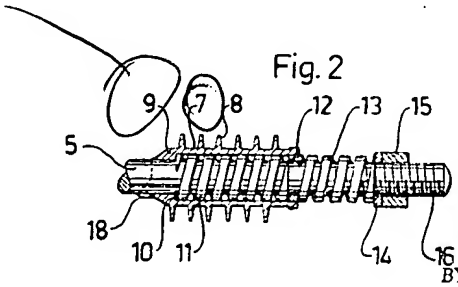


Fig. 2



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3,051,169

SURGICAL SCREW CONNECTOR

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5 Claims. (Cl. 128—92)

This invention relates to means for use in repairing fractures of bones of the body, and more particularly fractures of the neck of the leg bone or femur. In operations involving these parts, it is known to use screw connections between the fractured parts and by the use of spring means the broken parts are forced together and the healing thereby facilitated and expedited.

It is an object of the present invention to provide a type of screw or pin connector which includes a screw adapted to be inserted through the upper part of a femur in the direction of the femur head and to be anchored with its threaded end in the head. The invention further contemplates the employment of a sleeve or tube arranged around the screw and adapted to be fixed on the upper portion of the femur in a manner to guide the screw in movement in a radial direction, and it further includes a nut threaded on the outer end of the screw. Provided on the screw is a coil spring having one end in abutment against the sleeve and its other end bearing against the nut. Thus, by tightening the nut, the head of the femur at the neck or point of fracture, will be resiliently adjusted against the femur to thereby regulate the setting pressure to a predetermined extent.

A disadvantage often encountered with previous types of screw connectors has been that it was not always possible to obtain a constantly stable fastening to form the guidance for the screw, especially after the patient, following the operation, began to walk. Some types of connectors exhibited a tendency to give upon the imposition of increased weight, and this often resulted in the displacement of the broken parts at the point of fracture.

According to the present invention, this objection is eliminated by the fact that the sleeve employed as a part of this device, is provided with external threads, thereby permitting it, after the insertion of the screw in the bone, to be screwed or threaded in the bone to the depth required by the location and form of fracture. By this construction, a device is attained which requires considerably less space due to the fact that the usual extension of the sleeve, that in previous constructions was fastened on the outside of the bone, is eliminated. Furthermore, in the same prior constructions a part of the sleeve which housed a spring, projected to a substantial extent from the actual bone contour and often caused great discomfort to the patient. By a special formation of an externally threaded sleeve employed in this part, the device can accommodate a considerably longer spring than was used in prior constructions and without any part of the screw connector projecting to any real extent outside of the bone contour. By reason of this increased spring length it is possible to continue the spring pressure even after the broken parts have partially telescoped one another, and which sometimes results in a shortening of the femur neck.

With these and other objects to be hereinafter set forth in view, I have devised the arrangement of parts to be described and more particularly pointed out in the claims appended hereto.

In the accompanying drawing, wherein an illustrative embodiment of the invention is disclosed,

FIG. 1 is a side view, partly in section of the upper part of the fractured femur with an inserted screw connector made according to the present invention;

FIG. 2 is a longitudinal sectional view through the screw connector and in which the threaded inner part of the screw is omitted.

In FIG. 1 the femur bone is designated with the numeral 1; the ball head thereof indicated at 2, the neck shown at 4 and the fracture across the neck is designated by the numeral 3. The screw connector consists primarily of a screw 5, formed with threads 6 on its inner end which is threaded in and anchored in the ball head 2. The connector additionally includes a sleeve 7, fitted over the screw 5 and provided with external threads 8 which are threaded into the femur bone to the position substantially as shown in FIG. 1. The sleeve 7, at its inner end 9 (FIG. 2), is of such an internal diameter that it fits snugly around the unthreaded shaft portion of the screw 5, but for the remainder of its length it has a somewhat larger internal diameter in order to accommodate a helical spring 11 which is displaceable on the screw 5 and which is arranged with one end against the shoulder that forms the transition between the two different internal diameters of the sleeve. At the outer end, and in the drawing to the right, the sleeve 7 carries a spacing ring 12 which centers the sleeve 7 on the screw 5. Outside of the ring 12 is another helical spring 13 which, by means of an intermediate disk or washer 14, is supported against a nut 15 threadably adjustable on the threaded outer end 15 of the screw 5.

The connector is applied in the following manner:

After the broken bones are set in the proper position by means not pertinent to the present invention, a channel or passage is bored in the ball head 2 of the bone past the point of fracture 3 and which channel or passage has a diameter selected according to the diameter of the shaft of the screw 5. Thereafter a thread tap is inserted into the ball head 2 and which cuts threads corresponding to the threads 6. The screw 5 is then threaded into place in the ball head and thereafter the sleeve 7 is screwed into position therein.

Then the spring 11 is inserted around the screw 5 and within the sleeve, and the spacing ring fitted in place followed by the spring 13, the washer 14 and then the connector is tightened by means of the nut 15. The threads 8 on the sleeve and the threads 6 on the end area of the screw are preferably of the same pitch and this somewhat facilitates the threaded insertion of the parts into the bored channel or passage and also makes possible a simultaneous removal of the screw 5 and the sleeve 7 when the connector is to be removed. For this purpose, the screw 5 is provided at the end of the threads 6 toward its shaft, with a spur 17 or similar coupling element which, when the screw is unthreaded, engages with a corresponding spur 18 or other coupling device on the forward end of the sleeve 7 which faces the point of fracture 3 so that the sleeve will be carried along with the screw. As a result, the entire connector is removable as a unit without any further disturbance of the bone susbtance in the channel or passage. The screw 5 and the sleeve 7 are selected with a suitable length of the respective threads according to the location of the fracture 3, in order to provide the best possible anchorage.

Thus, in the situation shown, it is possible to use a screw with a comparatively large number of threads 6 while the number of threads on the sleeve 7 can be somewhat less. If the point of fracture should be located closer to the ball head 2, a screw should be selected with a less number of threads and with the sleeve having an increased number. Furthermore, as many springs 11 and 13 can be employed as each particular situation requires. The connector made according to the invention can therefore be provided in separate parts, which parts can readily be combined in the most suitable manner according to the individual requirements of each case.

A special advantage following from the construction of the sleeve 7 is that the total length of the springs can be considerably greater than those employed in previous constructions, so that the adjustment pressure can be regulated within certain limits without the connector projecting to any substantial extent outside of the contour of the bone as will be clear from FIG. 1. In many cases it is even possible to locate the connector entirely within the bone and in such cases the nut 15 may be threaded in sufficiently to cause it to enter the sleeve 7. The nut 15 must, in such a case, be made cylindrical and must have approximately the same outside diameter as the spacing ring 12 which it can then replace.

Having described a single embodiment of the invention, it is obvious that the same is not to be restricted thereto, but is broad enough to cover all structures coming within the scope of the annexed claims.

What I claim is:

1. A surgical screw connector for use in connection with fractures of the femur neck comprising, a screw inserted into the upper part of the femur in the direction of the ball head thereof, said screw having a threaded end anchored in the ball head, a sleeve arranged around the screw and fixed in the upper part of the femur and arranged to control any movement of the screw in a radial direction, a nut threaded on the outer end of the screw, helical springs displaceable on the screw and which springs abut at one end against the sleeve and abut at the other end against the nut, whereby the adjustment of the nut on the screw will cause the femur head at the point of fracture to be resiliently set against the femur, the sleeve having external threads so arranged that after the screw has been inserted into a previously prepared bore and the sleeve threaded therein to a position selected according to the location and shape of the fracture, a stable fastening will result.

2. A surgical screw connector for use in connection with fractures of the femur neck comprising, a screw inserted into the femur across the fracture therein, said screw having a threadless shank portion, a sleeve having a forward end of an internal diameter closely fitting around the shank of the screw, the sleeve having external threads of a pitch similar to the pitch of the threads on the screw, the sleeve having an internal diameter rearwardly of its forward end of a size substantially greater than the diameter of the screw, a spring located within the sleeve and surrounding the shank of the screw, means closing the rear end of the sleeve and confining the spring within the sleeve, an adjusting nut on the screw rearwardly of the sleeve-closing means, and a spring surrounding the shank of the screw between the said sleeve-closing means and the adjusting nut, and co-operating means on the screw and sleeve to cause unthreading movement of the sleeve when the screw is unthreaded.

3. A surgical screw connector for use in connection with fractures of the femur comprising, a screw inserted into the femur and across the fracture therein, said screw having a forward externally-threaded portion and with a

rear externally-threaded portion and provided with a threadless portion between the forward and rear threaded portions, a sleeve having a forward end of an internal diameter closely fitting the shank of the screw over the threadless portion thereof, said sleeve having external threads of a pitch similar to the threads on the forward portion of the screw, the sleeve having an internal diameter rearwardly of its forward end of a size substantially greater than the diameter of the threadless part of the screw, an annular shoulder provided within the sleeve adjacent to its forward end, a spring located within the sleeve and encircling the shank of the screw and having one end bearing against the shoulder, a disc closing the rear end of the sleeve, the second end of the spring bearing against the disc, a second spring surrounding the screw to the rear of the sleeve, said second spring having one end bearing against the disc, and an adjusting nut on the threaded rear portion of the screw and against which the second end of the second spring bears.

4. A surgical screw connector for use in connection with fractures of the femur neck comprising, a screw inserted into the upper part of the femur in the direction of the ball head thereof, said screw having a threaded end anchored in the ball head, a sleeve arranged around the screw and fixed in the upper part of the femur and arranged to control any movement of the screw in a radial direction, a nut threaded on the outer end of the screw, helical springs displaceable on the screw and which springs abut at the other end against the nut, whereby the adjustment of the nut on the screw will cause the femur head at the point of fracture to be resiliently set against the femur, the sleeve having external threads of the same pitch as the threads on the screw, the threads on the sleeve being so arranged that after the screw has been inserted into a previously prepared bore and the sleeve threaded therein to a position selected according to the location and shape of the fracture, a stable fastening will result, the screw and the sleeve being provided with interengaging coupling members operative to cause unthreading movement of both the screw and sleeve upon removal of the connector.

5. A surgical screw connector as provided for in claim 4, wherein the interengaging coupling members consist of a projecting spur provided on the screw and a co-operating spur provided at the forward end of the sleeve, said spurs being brought into engagement upon unthreading movement of the screw to thereby result in unthreading movement of the sleeve in company with the screw.

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Devas

[11] **4,059,102**

[45] **Nov. 22, 1977**

[54] **BONE SECURING DEVICES**

[75] Inventor: **Michael Bertrand Devas,** Bexhill-on-Sea, England

[73] Assignee: **National Research Development Corporation,** London, England

[21] Appl. No.: **727,995**

[22] Filed: **Sept. 30, 1976**

Related U.S. Application Data

[63] Continuation of Ser. No. 599,074, July 25, 1975, abandoned.

[30] **Foreign Application Priority Data**

Aug. 1, 1974 United Kingdom 34014/74

[51] **Int. Cl.**[2] **A61F 5/04**

[52] **U.S. Cl.** ..... **128/92 B**

[58] **Field of Search** ..... 128/92 B, 92 BA, 92 BB, 128/92 BC, 92 R, 83

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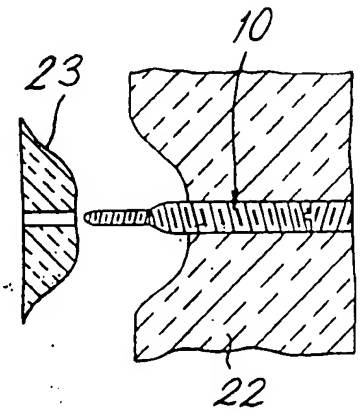
Primary Examiner—John D. Yasko

Attorney, Agent, or Firm—Cushman, Darby & Cushman

[57] **ABSTRACT**

A bone screw is provided having leading and trailing end portions with respective threads of opposite hands. The leading end portion will normally be narrower than the trailing end portion, and either or both portions can be tapered towards their leading ends.

2 Claims, 6 Drawing Figures



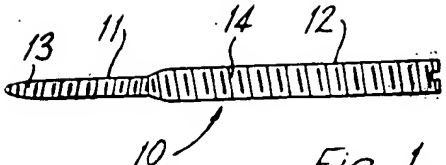


Fig. 1

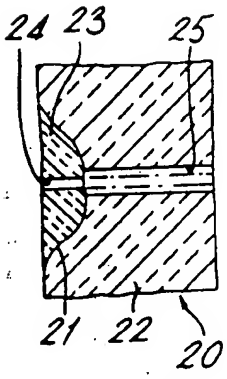


Fig. 2

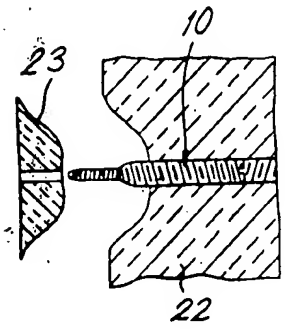


Fig. 3

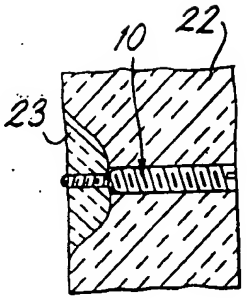


Fig. 4

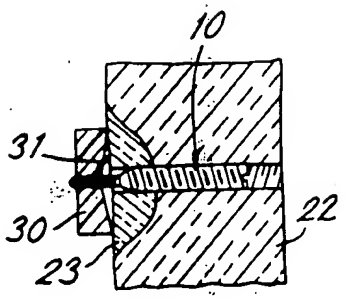


Fig. 5

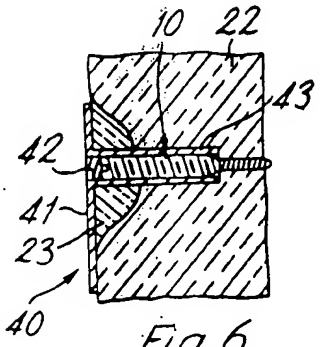


Fig. 6

BONE SECURING DEVICES

This application is a continuation of my copending application Ser. No. 599,074, filed July 25, 1975, which was abandoned when this application was accorded its filing date.

This invention concerns bone securing devices and more particularly bone screws such as used for fracture fixation, usually in association with bone plates and other endoprosthetic devices.

Apart from specific differences which may arise from a choice of particular material to suit the environment in which the screws are to be used, or choice of particular threads to suit the mechanical properties of bone, currently available bone screws are not essentially different in form and function from other screws.

As such, a bone screw is conventional in its inability to connect together two non-rotatable component parts, be they fractured bone parts or one such part and an ancillary device, such that the screw itself threadably engages with both parts and at the same time exerts a compressive force between the parts. This compound function only arises when one of the component parts rotates in the manner of a nut, but bone screws are normally used in a situation where the component parts are to be retained in predetermined dispositions.

However, this is not to say that the relevant compound function would not be useful. On the contrary, threaded engagement with a component part is normally desirable to enhance securement and distribute load, while compression between component parts enhances bone union after fracture fixation. Accordingly, any possibility of achieving both functions from a bone screw is clearly useful in various situations.

An object of the present invention is to realize this possibility and to this end the invention provides a bone screw having a first thread of one hand extending from one end of the screw over a leading longitudinal portion thereof, and second thread of opposite hand extending over a trailing longitudinal portion of the screw.

In the use of such a screw, the same is screwed by use of the second thread into and through a first component part to be engaged thereby, towards the second such component, this action positioning the trailing end of the screw within the first component part. Then this screw action is reversed to engage the leading end of the screw with the second component part by way of the first thread. Thus both component parts are threadably engaged with the screw, and the two component parts are drawn together under compression both by the screwing action into the second component part and the unscrewing action in the first component part.

In so far as the trailing end of the screw passes into a component part during use, there normally will be no enlarged head at the trailing end. Correspondingly, in so far as the leading end portion passes through the site to be engaged by the trailing end portion, the former normally will be of smaller diameter than the latter.

Also, since either of the leading and trailing end portions can be used to cut a thread in a component part, typically when this is bone, or to mesh with a correspondingly threaded part, typically when this is a bone plate or similar device, either of these portions of the screw can be tapered towards its leading end.

For a clearer and fuller understanding of the present invention, the same will now be described by way of

example with reference to the accompanying drawings, in which:

FIG. 1 illustrates one embodiment of the present invention,

FIGS. 2 to 4 illustrate one use of the embodiment of FIG. 1 and

FIGS. 5 and 6 respectively illustrate further uses of the embodiment of FIG. 1 in association with different ancillary devices.

The bone screw of FIG. 1 is denoted generally at **10**, and has a leading end portion **11** and a trailing end portion **12** respectively formed with first and second threads **13** and **14** of opposite hand. Each of the portions **11** and **12** is of nominally cylindrical form with a convergent tapering towards its leading end, the portion **12** being of larger diameter than portion **11**, and portion **12** being formed with a screw-driver engageable slot **15** at its trailing end.

One mode of use of the screw of FIG. **1** is illustrated by FIGS. 2 to 4 which show a bone **20** fractured at **21** into two component parts **22** and **23**.

FIG. 2 shows the bone 20 drilled to provide a pilot bore **24** which passes successively through the component parts 22 and **23** when correctly mutually located, with part 23 then being counterbored to provide an enlarged bore **25**.

FIG. 3 shows the part **23** separated from part **22**, and the screw 20 screwed into the part **22**, towards part **23**, by use of the thread **14**. In this connection, it is to be noted that the counterboring of part **22** provides a bore **25** which serves as a pilot bore relative to screw portion **12** with its thread **14**, while serving as an effective clearance bore for screw portion **11** with its opposite thread **13**. Also, it will be noted that this first screw action is continued until the trailing end of the screw is located within the bone part **22**, with the leading end portion **11** of the screw projecting into the space normally occupied by the bone part **23**.

FIG. 4 illustrates the result of a second screw action, whereby the pilot bore **24** in bone part **23** is applied to the screw leading end and the screw then rescrewed in the opposite sense to that of the first screw action. This reversed screw action screws the leading end portion **11** into bone part **23** by use of the thread **13** and, at the same time, withdraws the trailing end portion **12** by use of its thread **14** relative to bone part **22**. In the result, bone part 23 is drawn rapidly towards bone part **22** and these parts held together under compression, while each part is threadably engaged by the screw. Moreover, it is to be noted that an appropriate choice of dimensions for the screw allows the same to be wholly located within the confines of the bone.

This mode of use is particularly useful for fracture fixation in a situation where a relatively small fragment of bone is to be united with a main body of bone in the region of a joint. However, the screw of FIG. **1** is not limited to such a use, but can find other applications. One example of an alternative use is illustrated by FIG. **5**.

In FIG. 5 the screw 10 is used in a similar situation to that of FIG. 2, but in association with an ancillary device **30** in the form of a resilient disc or plate of plastics material such as high density polyethylene having one face **31** concavely dished. In this case, the device **30** effectively serves the role of bone part **23** relative to the screw and is provided with the pilot bore **25**, while the bone part 23 is formed with an extension of bore **25**. Thus, in FIG. 5, the screw trailing end portion is first

engaged with bone part 22 as before, and the leading end is passed through bone part 23 to screw into the device 30 by the subsequent reverse action, the device being located with its concave face adjacent the bone. In the result, the screw is engaged with the bone part 22 and the device 30, while the bone part 23 is held therebetween under compression in appropriate location with part 22.

The use of a plastics material and dishing for device 30 is advantageous in readily affording resilience to allow enhanced compression without damage of the bone by the device, and in allowing a self-tapping action by the screw with resultant economy in production of the device.

As to circumstances of use in which a device such as 30 is appropriate: these include situations in which the mechanical quality of the bone is inadequate to afford sound screw securement except within a relatively extensive body of such bone.

FIG. 6 illustrates a further example of use of the screw 10 in association with a different form of ancillary device denoted generally at 40. The device 40 serves the role of a bone plate which usually takes the form of a rigid strip apertured for passage of bone screws therethrough. In this case, device 40 includes such a strip 41 with at least one of the apertures 42 being extended from one side of the strip by a tube 43 which is internally threaded to co-operate with the thread 14 of the screw 10.

FIG. 6 shows the device 40 located with its strip 41 alongside the bone 20 with the tube 43 received in the bone part 22, and the screw to extend through the device and bone with its threads 13 and 14 respectively engaged with bone part 23 and tube 22. This situation is similar to that of FIG. 5, but with the relevant ancillary devices co-operating with opposite ends of the screw, and the procedure of use will be evident from the earlier discussion.

While the proposed screw has been described with more particular reference to the illustrated embodiment having a variety of uses, the screw itself can equally be varied. For example, when used with an ancillary device, such as 40 in FIG. 6, which is threaded to co-operate with the screw, the relevant screw portion clearly need not be tapered. Moreover this is relevant to either the leading or trailing portion of the screw since both portions can co-operate with such a device. Also, it is not essential that the trailing portion of the screw have a larger diameter than the leading portion, since both portions can co-operate with respective threaded ancillary devices in a single reverse screwing action to withdraw into one at the trailing end and advance into the other at the leading end.

I claim:

1. A new use for a screw of the type which has a leading end portion with a thread of one hand therearound and a trailing end portion with a thread of opposite hand therearound,

said new use being to connect together two mutually nonrotatable component parts, each of which is one of a fragment of a fractured bone and a fracture fixation device for disposition against said bone and said new use comprising the method of:

screwing one of said end portions of said screw into one of said component parts, and

then screwing the other of said screw end portions into the other of said component parts while partially unscrewing said screw from said one component part to locate said screw through said bone and to effect compressive force on said bone between said component parts.

2. The use according to claim 1 wherein said leading end portion is of lesser diameter than said trailing end portion, said one component part is provided with a bore which is a clearance fit for said leading end portion but not for said trailing end portion, said screw is applied with said leading end portion foremost to said bore, said trailing end portion is screwed into said bore to project said leading end portion from the remote end of said bore, and said leading end portion is thereafter screwed into said other component part.

* * * * *

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United States Patent [19]

Sekel

[11] Patent Number: 5,580,352

[45] Date of Patent: Dec. 3, 1996

[54] **DISTAL SHAFT WITH FAST AND SLOW SCREW THREADS**

[76] Inventor: **Ronald Sekel**, 42 Montgomery Street, Kogarah, NSW 2217, Australia

[21] Appl. No.: **952,515**

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[86] PCT No.: **PCT/AU91/00244**

§ 371 Date: **Feb. 1, 1993**

§ 102(e) Date: **Feb. 1, 1993**

[87] PCT Pub. No.: **WO91/18559**

PCT Pub. Date: **Dec. 12, 1991**

[30] **Foreign Application Priority Data**

Jun. 6, 1990 [AU] Australia PK0508

[51] **Int. Cl.**[6] **A61F 2/32**; A61F 5/00

[52] **U.S. Cl.** **623/23**; 623/18; 606/62

[58] **Field of Search** 623/16, 18, 19, 623/22, 23; 606/72, 73

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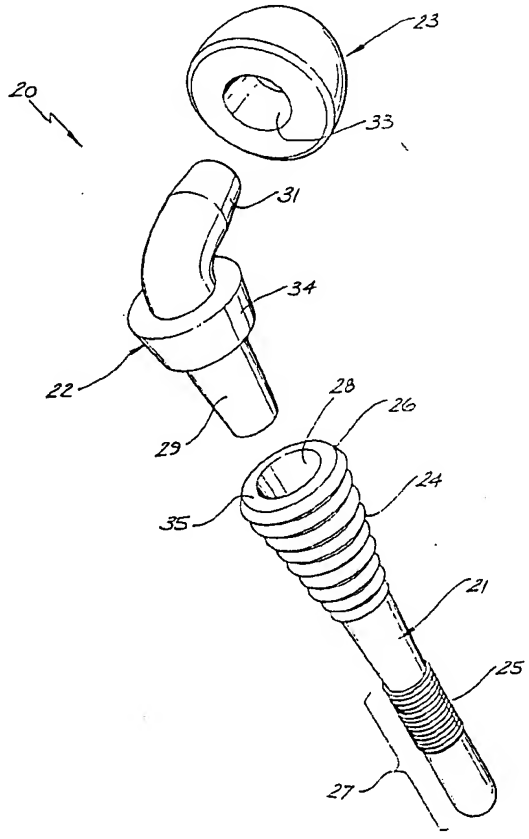
Primary Examiner—David Isabella

Attorney, Agent, or Firm—McAulay Fisher Nissen Goldberg & Kiel, LLP

[57] **ABSTRACT**

A femoral prosthesis adapted for insertion into the medullary cavity of a femur. The prosthesis including a distal shaft, a neck portion detachable from the distal shaft and a joint head detachable from the neck portion. The distal shaft having two spaced tapered threaded portion thereabout with differing pitch to prevent undesired counter rotation of the prosthesis thereby preventing axial withdrawal of the distal shaft from the femur.

10 Claims, 5 Drawing Sheets



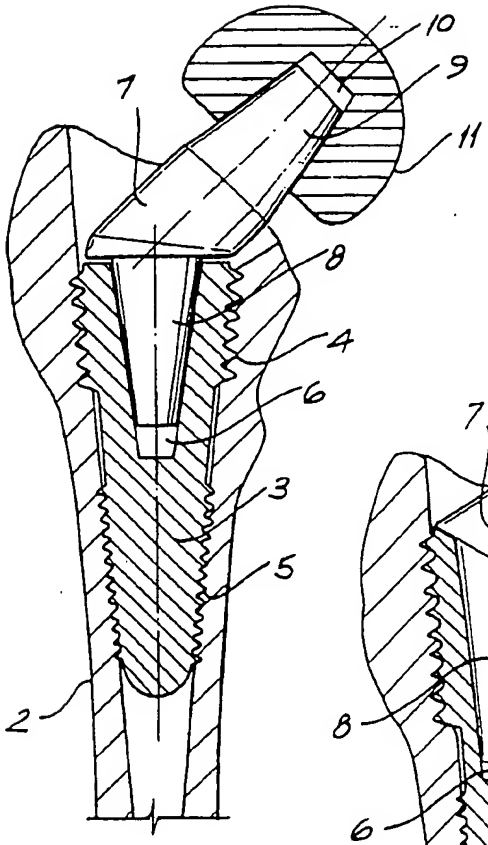


FIG. 1

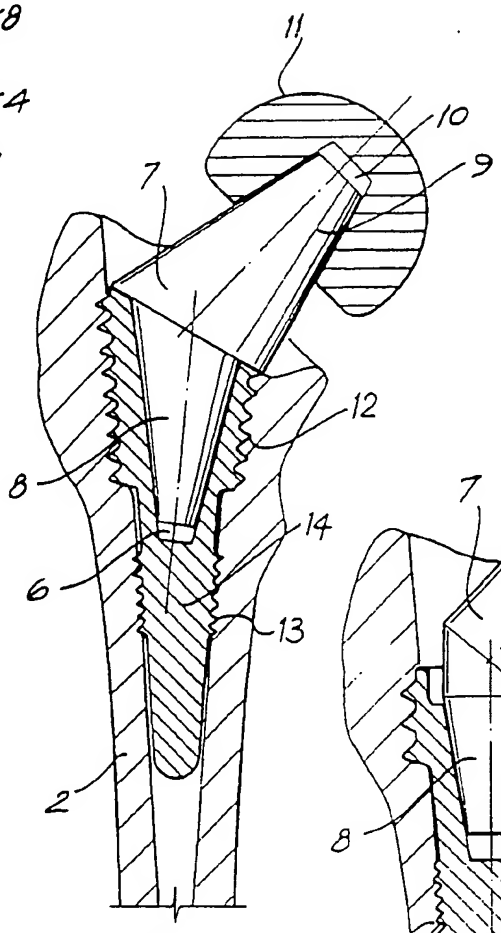


FIG. 2

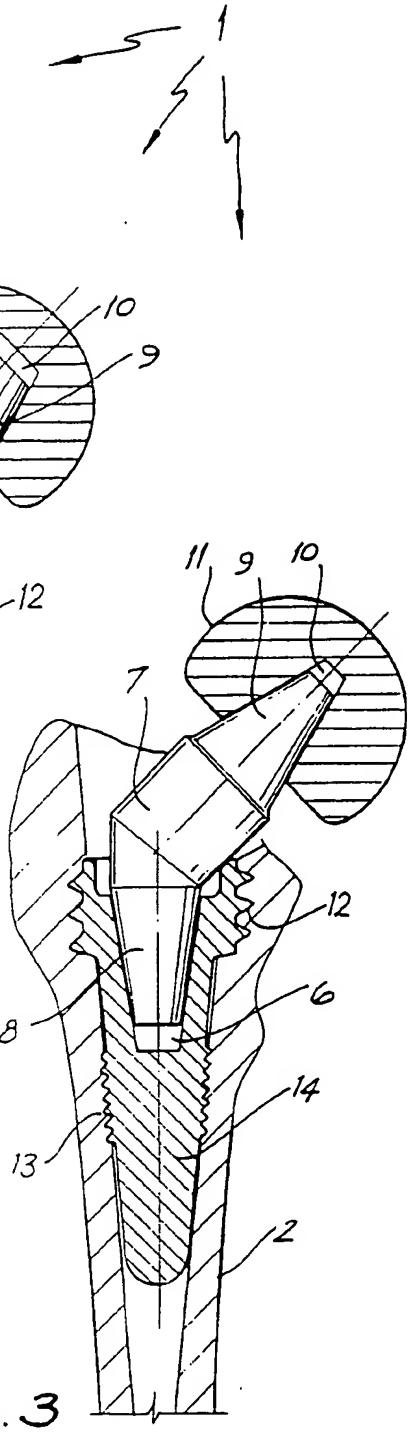


FIG. 3

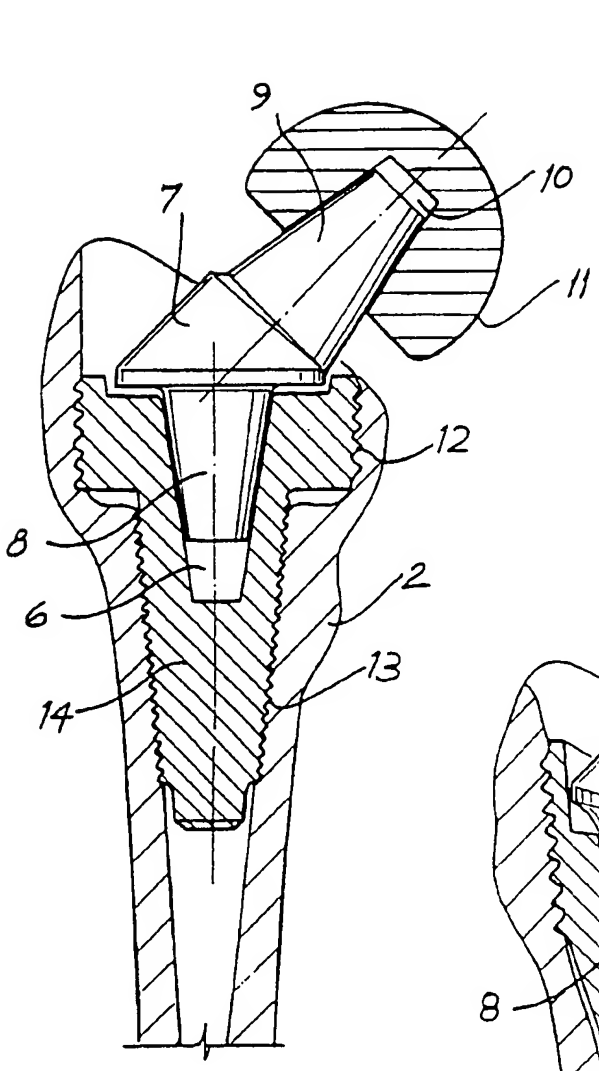


FIG. 4

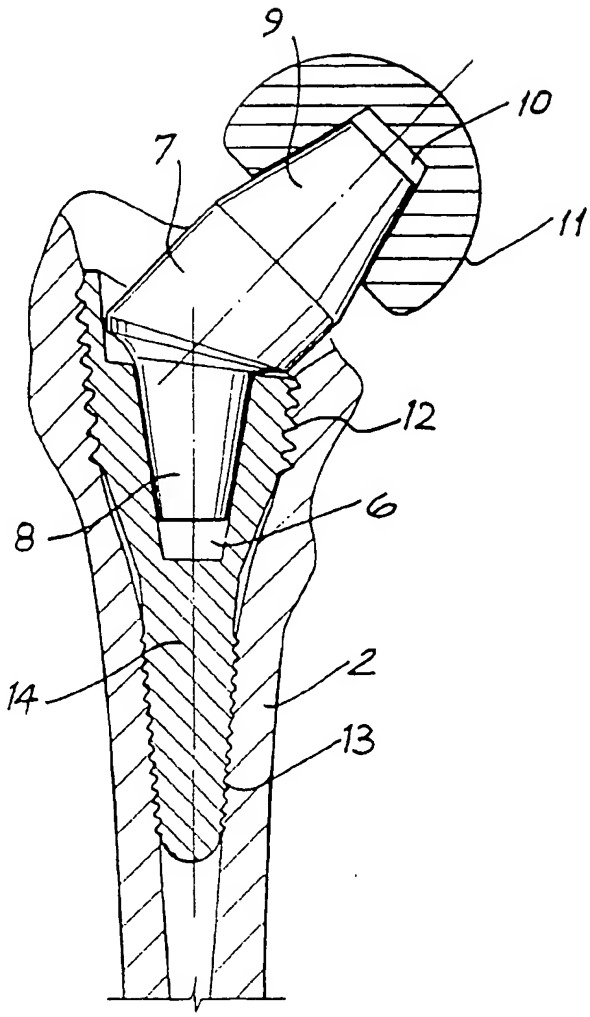


FIG. 5

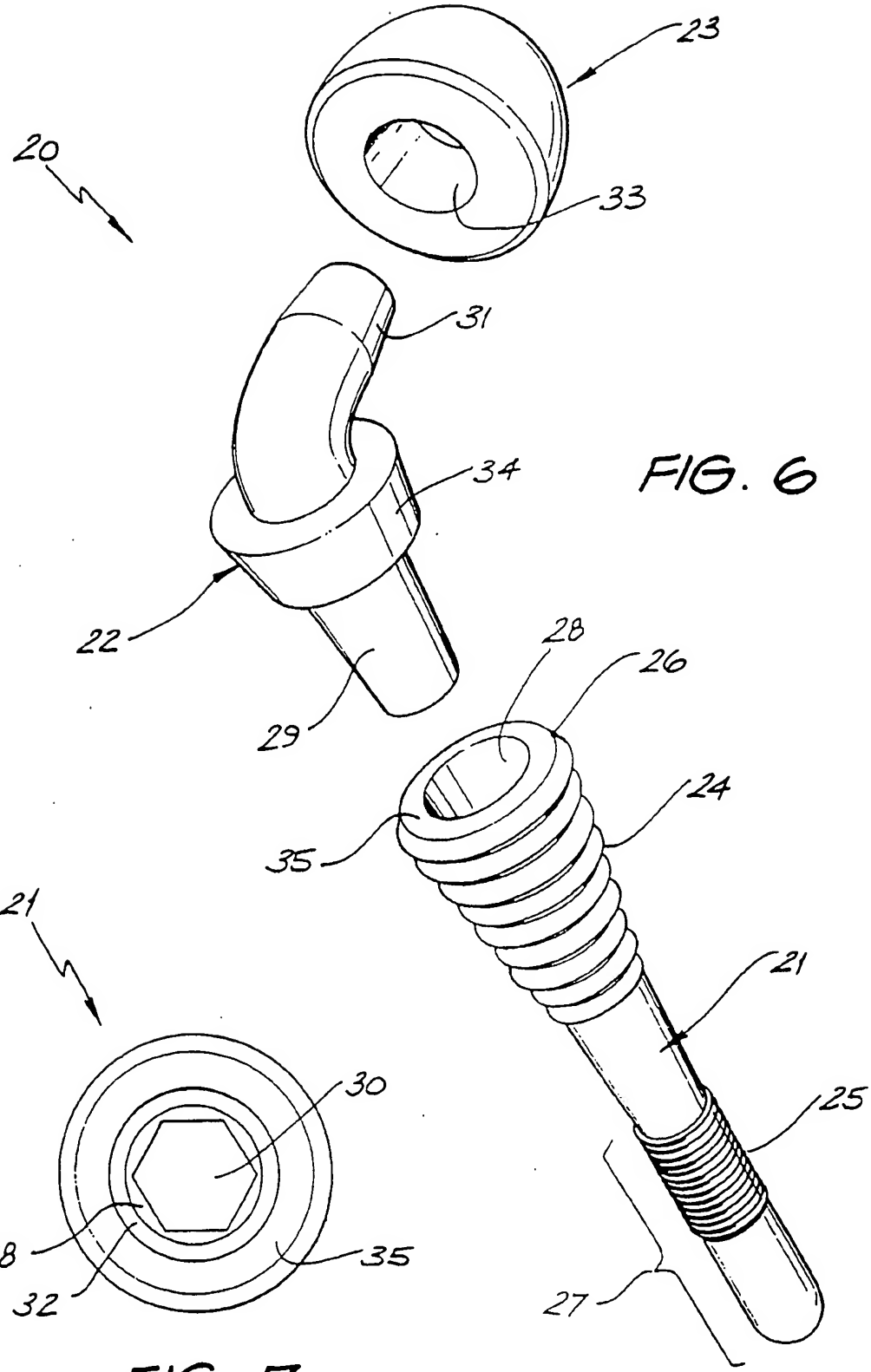


FIG. 6

FIG. 7

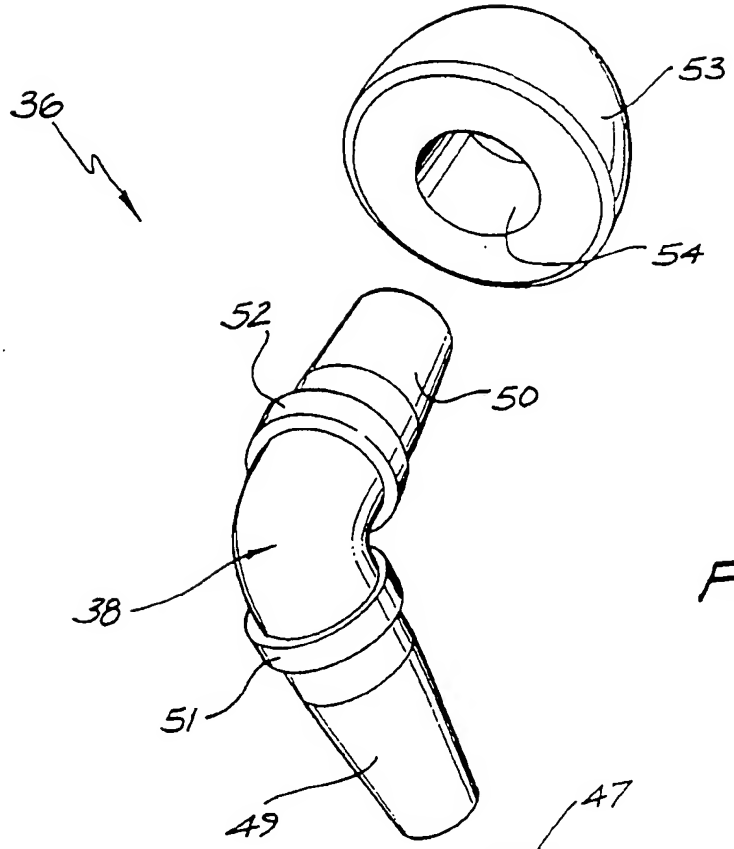


FIG. 8

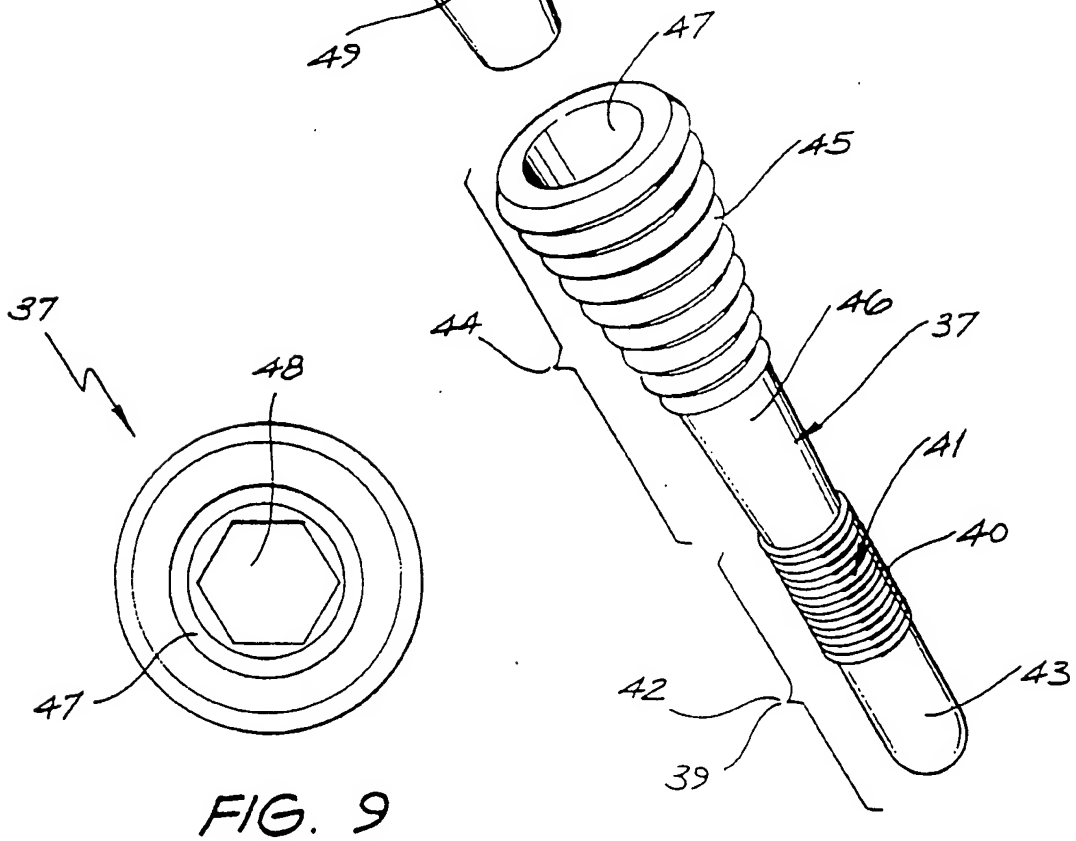


FIG. 9

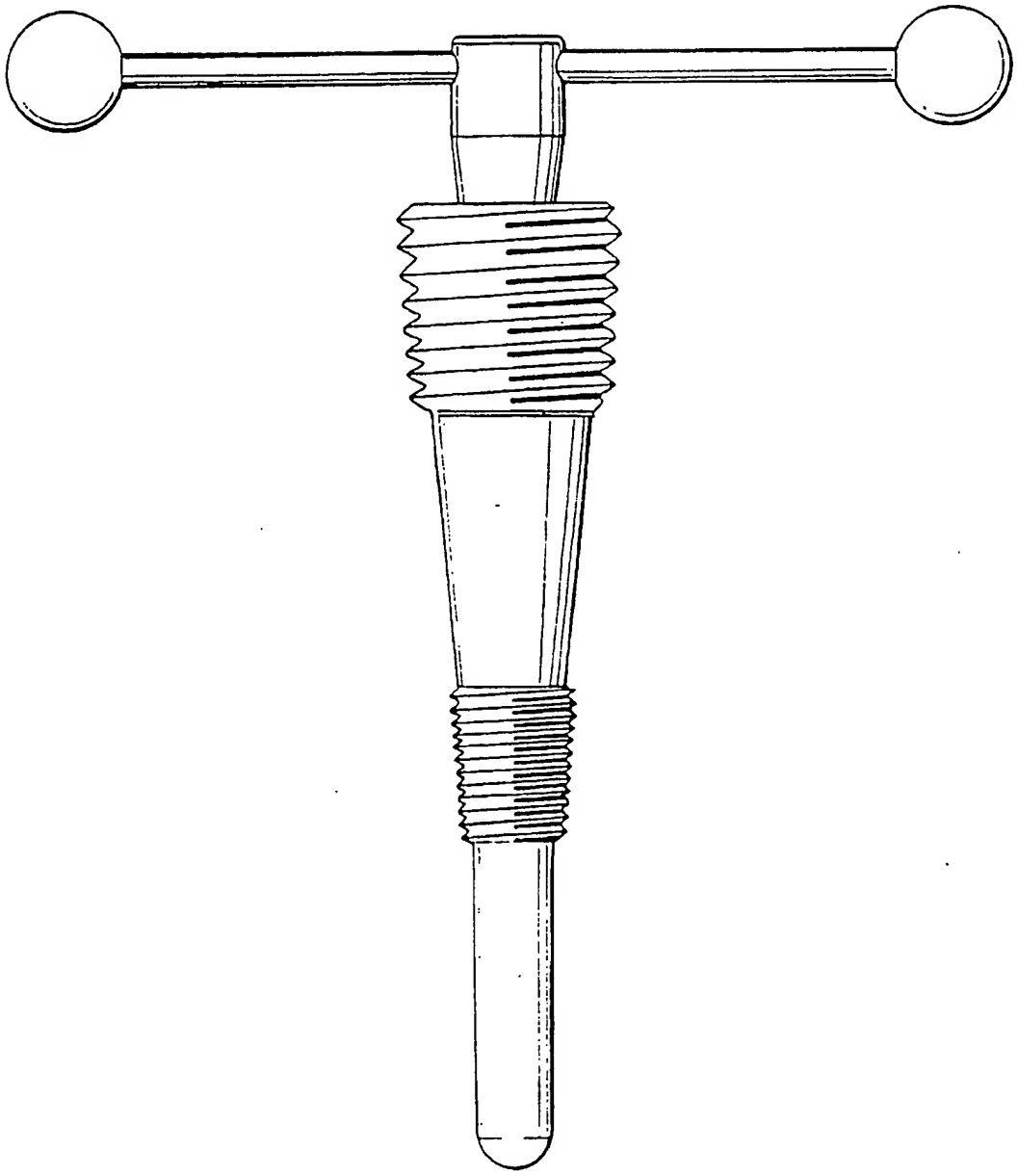


FIG. 10

DISTAL SHAFT WITH FAST AND SLOW SCREW THREADS

The present invention relates to surgical prostheses and more particularly, relates to a femoral component for use in hip replacements either at first instance or in revision hip operations following an earlier implant failure.

Hip replacements are a common orthopaedic surgical procedure and are usually necessitated by degenerative disease of the hip joint, hip trauma or disease of the hip creating later hip trauma.

In a total hip replacement, the surgical procedure may involve reaming of the acetabulum, reaming of the proximal medullary cavity of the femur and inserting a prosthesis into the said medullary cavity to replace the natural femoral head.

The head of the prosthesis (usually formed by a detachable ceramic ball) mates with the acetabulum in the same manner that the natural femoral head mates with the acetabulum in a normal hip joint.

Depending upon the dictates of the pathology of the joint not all hip replacements require reaming of the acetabulum. In some cases only the femoral head requires replacement; for example, in a fractured neck of femur. The invention may be used in hemiarthroplasty or as the femoral component of a total hip arthroplasty.

There are in existence a number of hip prostheses which have been used to replace the femoral head. Whilst each of the prior art femoral head prostheses have enjoyed widespread use with varying degrees of success, each have suffered from certain attendant disadvantages.

One generally known and widely used prosthesis typically comprises an arcuate distal shaft having a gradual taper along its full length and terminating proximally in a neck which mates with the head of the prosthesis via a Morse taper. The shaft is inserted into the indra medullary cavity of the femur.

This prosthesis is fitted after the surgeon has reamed out the medullary cavity to an extent conducive to the production of tight interfitting between bone and prosthesis when the prosthesis is hammered into position. In practice, the reaming followed by sizing with the prosthesis may be carried out a number of times i.e., reaming followed by inserting the prosthesis until there is a small distance of travel of the shaft left near the neck of the femur to enable final hammering into position to thereby create tight interfitting between prosthesis and bone. In the final stages of this procedure, when the prosthesis is hammered home, care must be taken by the surgeon to avoid exploding the femur by creating hoop stresses beyond the modulus of elasticity of the bone. The tolerable limits of bone elasticity are guaged mainly by the experience of and feel by the surgeon.

Femoral explosion is one major drawback when using this prior art prosthesis both during insertion and extraction, however, explosion during insertion is largely due to poor surgical technique.

In the past, cementing of the prosthesis has also been employed, however, problems have existed with the use of cement. Failures in hip prostheses have occurred due to loosening at the cement bone interface and at the prosthesis bone interface. In some patients, a rotational failure of the prosthesis can be generated when a patient moves from a seating to a standing position.

Also, artificial hips may loosen and fail due to repetitive movement of the distal shaft induced by the locomotion of a wearer. This may eventually lead to a prosthesis failure and possibly unwanted axial dislocation; for example subsidence of the prosthesis.

One feature of the existing prostheses is a series of indentations which have been moulded into the distal shaft in order to encourage and stimulate bone growth therein. This bone ingrowth assists in holding the prosthesis firmly in position and also provides a keying and locking effect thereby lessening the possibility of rotational failure and/or unwanted axial subsidence of the prosthesis.

A further problem which exists with this type of prior art prosthesis and in particular with the distal shaft design is the difficulty in removal from the medullary cavity of a failed prosthesis. The procedure to replace a failed prosthesis, known as a revision hip replacement, necessitates full extraction of the failed prosthesis from the medullary cavity. Where the prosthesis has been held in position by bone growth into the aforesaid recesses of the distal shaft, extraction of the prosthesis can sometimes be extremely difficult, and in some unfortunate instances, may necessitate total longitudinal division of the femur into at least two pieces. Even after division of the femur in this way, a particularly recalcitrant prosthesis firmly affixed to one half of the bone may, in order to effect removal thereof, necessitate further undesirable femoral destruction. After removal of the failed prosthesis by femoral destruction, the divided femoral bones must then be rewired and/or screwed. A new prosthesis can be inserted either before the bones are rewired or after rewiring in accordance with normal procedure.

Clearly this surgical problem is wholly undesirable and results in increased theatre time and an increased period of convalescence for a patient as the divided bone requires additional time to heal.

Whilst prostheses of this type have been in use for some time and have met with considerable field success, the attendant disadvantages of the device are so significant that improvements are necessitated.

Other prosthesis designs are also used having screw threads on the distal shaft however, these suffer from the major disadvantage that it is very difficult for the surgeon to achieve, co-incidence between the correct orientation of the prosthesis at full screw tightness and proper alignment or anteversion between the prosthesis head and the acetabulum. This requires considerable skill on the part of the surgeon with very little margin for error due to the critical alignment and screw tightness requirements. For this reason surgeons have not utilised the screw prostheses as much as the previously described prosthesis. A further disadvantage of the existing screw prosthesis is its poor resistance to rotational effects which can result in unwanted reverse rotational withdrawal from the femoral medullary cavity. This in turn upsets the critical anteversion between femoral head and acetabulum thereby often resulting in the need for a revision hip operation. The withdrawal by unscrewing of this prosthesis does nevertheless have an advantage in revision hip operations where the existing prosthesis is to be withdrawn and removed by the surgeon however, the problem of unwanted reverse rotation of an in situ screw prosthesis is too great in proportion to the advantage provided by the single screw thread. Prior art prostheses employing single screw threads have thus been quite unsatisfactory resulting in their limited use.

The present invention seeks to ameliorate or eliminate the attendant disadvantages which have been manifest in use of the prior art hip prostheses by providing an improved prosthesis.

In addition to providing significant advantages over the prior art, the present invention overcomes the problems associated with, unwanted withdrawal of screw thread prostheses, obtaining of correct anteversion of screw thread prostheses with the acetabulum at full screw tightness, and problem extractions of prostheses during revision hips.

The invention combines the benefits of the known prior art prostheses, provides further benefits and eliminates the prior art disadvantages.

In its broadest form the present invention comprises; a femoral prosthesis of the type comprising a distal shaft neck and head and adapted for insertion into the medullary cavity of the femur to thereby form a replacement for the natural femoral head; characterised in that the femoral prosthesis comprises;

a first threaded portion and a second threaded portion on said distal shaft with a cavity at one end of said distal shaft,

a detachable member adapted to mate at one of its ends with the said cavity and adapted at its other end to mate with an artificial head,

whereupon when said distal shaft is inserted into and fixed in situ the medullary cavity of the femur correct anteversion between said head and the acetabulum of a patent is effected by relative rotational movement between said detachable member and said distal shaft.

In another broad form the present invention comprises; a femoral prosthesis of the type adapted for insertion into the medullary cavity of the femur to thereby form a replacement for the femoral head characterised in that the femoral prosthesis comprises;

a distal shaft having at least one threaded portion thereon and a cavity at one end,

a member configured to interfit via one end within said cavity and via the other end to interfit with an artificial head wherein when

said distal shaft, said member and said artificial head are mated together, an artificial hip is thereby formed.

In another form the invention comprises a femoral prosthesis of the type adapted for insertion into the medullary cavity of the femur to thereby form a replacement for the femoral head or hip; characterised in that the femoral prosthesis comprises a distal shaft having at least two different pitch screw threads thereabout, said distal shaft terminating at one end in a neck portion configured to receive an elbow member to thereby form in conjunction with a head portion an artificial hip.

In its broadest form the present invention comprises a femoral prosthesis comprising a threaded distal shaft, a detachable elbow having a double Morse taper and a head.

In one broad form the present invention comprises:

a femoral prosthesis adapted for insertion into the modullary cavity of a femur said prosthesis comprising, a distal shaft, a neck portion detachable from said distal shaft and a head detachable from said neck portion characterised in that the neck portion comprises an elbow having means at either end to enable male female or female male mating with said distal shaft and also with said head to create tight interfitting therebetween, said elbow being rotatable relative to said shaft and head prior to effecting said tight interfitting and while said distal shaft is fixed in situ.

In another broad form the invention comprises:

A femoral prosthesis adapted for insertion into the medullary cavity of a femur said prosthesis comprising a distal shaft, a neck and a head; characterised in that the distal shaft comprises first and second spaced apart threaded regions thereon.

In an alternative form the present invention comprises:

A distal shaft for use in a femoral prosthesis said shaft having a recess at the proximal end adapted to receive a tapered portion on an elbow said shaft also comprising spaced apart threaded portions.

In a further form the invention comprises:

An elbow for use in a femoral prosthesis said elbow comprising two legs disposed at an obtuse angle to each other, each of said legs terminating at its extremity in a tapered portion.

In one preferred embodiment the invention comprises a tapered distal shaft having two spaced apart tapered threaded portions thereabout with differing pitch and a female tapered cavity at one end adapted to detachably receive a first male part of a corresponding mating member in a tight interfitting relationship, with the mating member also having a second male part adapted to tightly interfit with a female cavity in a head member.

Preferably the interfitting between the first and second male parts and the corresponding female parts is effected by a Morse taper at either end of the mating member, thereby creating a double MORSE taper, allowing interengagement between the distal shaft and the mating member and between the mating member and an acetabular cup.

Although the prosthesis is ideally intended to be formed by detachable communication between the distal shaft and an elbow having means thereon which forms double MORSE taper connections, the prosthesis may be fabricated in one piece with two threads on the distal shaft with the shaft terminating in a single Morse taper which engages the head member.

The present invention will now be described in more detail according to a preferred but non limiting embodiment and with reference to the accompanying illustrations wherein;

FIG. 1 shows a long sectional view of the proximal portion of a femur with an assembled prosthesis of the present invention inserted therein according to a preferred embodiment.

FIG. 2 shows a long sectional view of the upper portion of a femur with a prosthesis according to an alternative embodiment inserted therein.

FIGS. 3, 4 and 5 show various embodiments of the prosthesis of the present invention.

FIG. 6 shows an exploded view of a prosthesis according to a preferred embodiment.

FIG. 7 shows a plan view of the distal shaft of FIG. 6.

FIG. 8 shows an exploded view of a prosthesis according to a preferred embodiment of the invention.

FIG. 9 shows a plan view of the distal shaft of FIG. 8.

FIG. 10 shows a tool which may typically be used in preparation of the medullary cavity to receive the prosthesis.

Referring to FIG. 1 there is shown a prosthesis 1 located proximally in femoral long section 2.

The prosthesis according to the embodiment of FIG. 1 essentially comprises a distal shaft 3 having two spaced apart threads 4 and 5 disposed helically and peripherally about the longitudinal axis of the shaft. The distal shaft 3 has a reducing taper with the thread 4 thereabout having a fast helix and the thread 5 having a slow helix effected by differing thread pitch.

At the upper end of the distal shaft there exists a tapered recess 6. The recess 6 is adapted to receive an elbow or neck 7 which has a tapered male profile part 8 which taper is the reverse that of recess 6 to facilitate upon coupling a tight male/female interfitting therebetween. This type of connection is known as a Morse taper not hitherto previously known in this specific application.

The elbow 7 also comprises a tapered end forming a male profile part 9 which is adapted to mate with female recess 10 in head 11, thus forming a second Morse taper according to conventional usage.

In order to insert the prosthesis, the surgeon reams out the medullary cavity of the femur to enable mutual comparability between the bone and prosthesis. The reaming which takes place is commensurate with required thread depth and distal shaft width and taper. The bone cross section is reamed to approximately the width and length of the taper over the

thread length less the thread depth. Thus the reaming for slow thread **5** will be considerably less than that for fast thread **4**. The threading may be done preferably with a truncated cone threader similar to that shown in FIG. **10**. The shaft **3** is screwed into the medullary cavity and if necessary, with bone graft supplementation to ensure a strong prosthesis-bone bond. One major advantage of this prosthesis is the optional elimination of the need for cementing or precoating of the prosthesis. Although the prosthesis may be pre-coated with hydroxyapetite to stimulate bone ingrowth, this is not essential.

In practice, the distal shaft **3** is screwed into position following reaming using the truncated conical tool of FIG. **10** or an allen key with the assistance of a torque wrench. Once the distal shaft is in position, the elbow **7** may be inserted into cavity **6** and rotated by the surgeon to the correct position of alignment with the acetabulum (not shown). Once this position is determined, the elbow is hammered to effect the tight interfit with the distal shaft. The Morse taper prevents unwanted rotational and axial movement, once the elbow is aligned and driven home. Finally, the head **11** (a conventional ceramic, chrome cobalt, plastic or titanium cup) is hammered onto male profile part **10** of elbow **7** to complete the location of the prosthesis. The use of the double Morse tapered elbow allows rotational alignment of the head relative to the acetabulum or an acetabular cup after screwing in of the distal shaft **3** is complete, thereby enabling a convenient final fine adjustment of the prosthesis. The double threads on the distal shaft **3** create a compression force in the bone thereby removing the problem which existed in prior art 'screw in' prostheses of unwanted counter rotation leading to axial withdrawal of the distal shaft.

The use of the double Morse taper therefore allows the surgeon to conveniently achieve accurate anteversion of the femoral head and neck at the appropriate angle.

FIG. **2** shows an alternative embodiment of the prosthesis of FIG. **1**, this time with a first wide threaded portion **12** and a narrower threaded portion **13**. Fast thread **12** and thread **13** combine to create a compressive force to hold the distal shaft **14** firmly within the medullary cavity. This prosthesis may be implanted after medullary cavity preparation using the tool of FIG. **10** to prepare the thread paths.

FIGS. **3**, **4** and **5** show further alternative embodiments of the present invention. The threads thereon could be scinted, beaded or precoated.

Referring to FIG. **6** there is shown an exploded view of a femoral prosthesis **20** according a preferred embodiment of the invention. The prosthesis **20** comprises a distal shaft **21**, a detachable neck comprising an elbow **22** and a head **23**. The distal shaft **21** also comprises threaded portions **24** and **25** with threaded portion **24** being at or near the proximal end **26** of the distal shaft **21** and with the threaded portion **25** being spaced apart distally at location **27**. When the distal shaft is screwed into position as previously described the threaded portions **24** and **25** due to their respective helix configurations cause a compressive force to be exerted on the wall of the medullary cavity of the bone. This results in a strong implant with high rotational stability and high resistance to unwanted axial withdrawal due to rotational failure. Referring to FIG. **7** distal shaft **21** has a female recess **28** at the proximal end **26** for coupling with tapered male profile part **29** of elbow **22**. Distal shaft **21** also comprises a hexagonal profile **30** adapted to receive an allen key for unscrewing of the distal shaft when removal of same is required. Elbow **22** comprises tapered portions **29** and **31** which together form the neck of the prosthesis. Preferably tapered portion **29** is longer than tapered end **31** in view of the fact that the depth of penetration of tapered portion **29** is necessarily greater than that required for taper **31**. In use after the distal shaft **21** is secured in position by the surgeon, the elbow **22** is gently dropped into recess **28** whilst maintaining a sufficient degree of loseness for rotation of the elbow **22** relative to the distal shaft **21**. When the correct anteversion is determined by the surgeon, the elbow **22** is driven home to a condition of tight interfitting between taper **29** and the wall **32** of recess **28**. Taper **31** engages recess **33** of the head **23** to complete the femoral prosthesis assembly.

Elbow **22** is also adapted with a collar or flange **34** which provides a levering point to enable the surgeon to remove the elbow where the femoral prosthesis is to be removed from a patient. The surgeon may lever against the upper crest **35** of the distal shaft **21** and against the collar or flange **34** in order to break the tight interfitting. Collar **34** as shown is merely one embodiment for facilitating separation between elbow **22** and distal shaft **21**. It will be recognised that other means can be adapted to the elbow **22** in order to facilitate separation prior to removal of the distal shaft.

Referring to FIG. **8** there is shown an exploded view of a hip prosthesis **36** with more specific design geometry for the distal shaft **37** and the neck or elbow **38**.

FIG. **9** shows a plan view of the distal shaft **37**. At the distal end **39** of the shaft **37** is a screw thread **40** about a region **41** of constant width. The diameters of the distal shaft core **42** fall preferably within the range of 9 mm to 13 mm. The distal core **42** comprises the thread **40** and non threaded region **43**. Thread **40** is configured as a slow thread. Preferably the lengths of thread **40** and non threaded region **43** would be 35 mm and 22 mm respectively.

At the proximal region **44** of the distal shaft **37** is a tapered screw thread **45** and a non threaded tapered region **46** with the thread **45** approximately 40 mm in length and the region **46** approximating 33 mm in length. Thread **45** is configured as a fast helix relative to the helix of thread **40**. The proximal region **44** preferably has a 10 degree taper in order to approximate anatomical characteristics of the proximal medullary cavity of a femur. Preferably proximal core diameters are within the region 20 mm to 26 mm with the outside diameter including the thread being an additional 1 to 2.5 mm. Proximal region **44** of the shaft **37** is adapted with a Morse one taper **47**. Ideally a taper within the Morse range of ¾ to 1.5 is preferred however, this is not to be construed as a limiting parameter. The Morse taper **47** terminates in hexagonal recess **48** which provides means for insertion and deliberate withdrawal of the shaft **37** for instance, in the event of a revision hip operation.

Preferably, the distal shaft is made from Titanium or chrome-cobalt alloy with an hydroxyapetite coating being applied to the threaded regions to stimulate osteogenesis or bone ingrowth around the shaft **37**. Alternatively chrome cobalt with beading to stimulate bone ingrowth may be used.

In the prior art prosthesis distal shafts have relied upon boney ingrowth and/or circumferential point fixation in order to provide proper anchorage. Distal shafts which have been configured anatomically have often failed due to a lack of reliance on point fixation generating hoop stresses. Many of the prior art prostheses have been generally square or rectangular which has meant that due to the shape of the intramedullary cavity there is limited contact between prosthesis and bone hence localised force distribution.

The distal shaft **37** of the present invention increases the prosthesis bone contact area having a resultant more even contact force distribution. Prosthesis **36** also comprises elbow or neck **38** which is configured at an obtuse angle between 90° and 180°. Elbow **38** comprises a first Morse taper **49** and a second larger Morse taper **50**. The difference

in the tapers is to prevent an error in mating between the elbow **38** and the distal shaft **37**. Taper **49** is preferably a Morse 1 taper with second taper **50** being preferably Morse 1.5.

Elbow **48** is also adapted with collars **51** and **52** to facilitate release of the Morse tapers.

Morse 1 taper **49** engages taper **47** in distal shaft **37**. Taper **50** engages head **53** via a female recess **54** therein. Head **53** may generally be 28, 32 or 38 mm in diameter with an internal Morse taper of 1.5. Once the distal shaft is inserted by the surgeon the configuration of the elbow will enable accurate approximation of the distance in the particular patient from the midline of the femur to the correct location of the head **53** in the acetabulum or in the acetabular cup in the case of a total hip replacement. Thus the double Morse taper on the elbow leads the surgeon to the anatomical centre of the previous natural femoral head.

Appropriate anteversion may be achieved by the surgeon with the elbow **48** prior to wedging of taper **49** in the distal shaft taper **47**.

If the elbow is to be removed, the Morse taper is easily broken by levering or wedging against collar **51**. Similarly where head **53** is to be removed levering or wedging against collar **52** facilitates this.

Reaming of the medullarly cavity prior to fixation of the prosthesis results in distal fixation occurring along a plane normal to the cortex bone when a femur is viewed in long section. Proximal fixation occurs principally in a plane at 90° to that for distal fixation, anteriorly and posteriorly.

With the present invention the surgeon is more able to predict hoop stresses generated in fixation.

The distal shaft **37** may be lengthened where necessary especially where a fresh bone contact area is required if a previously used prosthesis fixation area has been degraded.

Similarly, the elbow may be adapted for lengthening by use of extension pieces so that the exact location of a removed anatomical head may be located.

The prosthesis of the present invention places some reliance on the compressive forces generated by the fast and slow threads along with the frictional resistence generated by bone prosthesis contact to resist axial dislocation of the prosthesis.

In order to guard against the unlikely event of reverse rotation of the prosthesis, a longitudinal channel may be formed along the medullary cavity wall to facilitate keying of the prosthesis to the bone. The key would need a corresponding longitudinal slot in the prosthesis shaft.

It will be recognised by persons skilled in the art that numerous variations and modifications may be made to the invention as broadly described herein without departing from the overall spirit and scope of the invention.

I claim:

1. A distal shaft for use with a hip prosthesis which includes a detachable elbow component and a detachable head component, the shaft being insertable wholly within and in axial alignment with a medullary cavity of a femur, the shaft having a flared proximal end provided with a tapered recess in axial alignment with the shaft for receiving the elbow component and also having a tapered distal end, the shaft being provided with a first helical thread and a second helical thread spaced apart from one another.

2. A distal shaft according to **claim 1** wherein the first thread is a wide tapered helical thread located proximately to the flared proximal end of the shaft and the second thread is a narrow helical thread disposed towards the narrow distal end of the shaft.

3. A distal shaft according to **claim 2** wherein the threads are equal in length with respect to the shaft.

4. A distal shaft according to **claim 2** wherein the threads are different in length with respect to the shaft.

5. A distal shaft according to **claim 1** wherein said first and second threads are structured to have different helix configurations such that when said shaft is inserted into the medullary cavity of a femur, said first and second threads induce a compression force into the femur.

6. A distal shaft according to **claim 5** wherein the said first thread and said second thread have similar pitches.

7. A distal shaft according to **claim 5** wherein the said first thread and said second thread have different pitches.

8. A distal shaft according to **claim 5** wherein the elbow component is capable of rotation relative to the shaft prior to effecting tight interfitting with the shaft.

9. A distal shaft according to **claim 5** wherein the tapered recess in the shaft is a Morse taper.

10. A distal shaft according to **claim 1** wherein the first and the second helical thread are spaced apart from one another by a threadless section of the shaft.

* * * * *

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United States Patent [19]

Pilliar et al.

[11] Patent Number: 5,344,457

[45] Date of Patent: Sep. 6, 1994

[54] POROUS SURFACED IMPLANT

[75] Inventors: Robert M. Pilliar; Douglas A. Deporter, both of Toronto; Phillip A. Watson, Don Mills, all of Canada

[73] Assignee: The University of Toronto Innovations Foundation, Ontario, Canada

[21] Appl. No.: 12,626

[22] Filed: Feb. 2, 1993

Related U.S. Application Data

[63] Continuation of Ser. No. 649,700, Feb. 1, 1991, abandoned, which is a continuation-in-part of Ser. No. 517,517, Apr. 26, 1990, abandoned, which is a continuation of Ser. No. 420,689, Oct. 11, 1989, abandoned, which is a continuation of Ser. No. 138,340, Dec. 28, 1987, abandoned, which is a continuation-in-part of Ser. No. 864,805, May 19, 1986, abandoned.

[51] Int. Cl.[5] A61F 2/28; A61C 8/00; A61C 13/10

[52] U.S. Cl. 623/16; 433/174; 433/175; 433/191; 433/193; 433/195

[58] Field of Search 433/172, 173, 174–176, 433/191–194; 623/16

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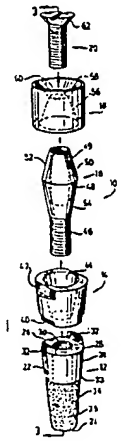
Primary Examiner—David Isabella
Assistant Examiner—Debra S. Brittingham
Attorney, Agent, or Firm—Wyatt, Gerber, Burke and Badie

[57] ABSTRACT

There is disclosed an implant for anchoring in bone and/or fibrous connective tissue and to which a prosthesis such as a dental bridge may be connected through connecting components. The implant is of tapered design defining a wide top portion for connection to the connecting components and a tapered body comprising upper and lower regions. The lower bone-engaging region of the implant is provided with a porous surface into which bone may grow thereby anchoring the implant. The upper region of the implant has a surface suitable for bone attachment which is different from the surface of the lower region. In one embodiment, the upper portion has a larger taper angle than the rest of the implant for increased stability and stress transfer to the surrounding bone. In another embodiment, the surface of the upper region is coated with a bioreactive coating to allow direct bonding of bone and/or soft connective tissue (gingival tissue) thereby inhibiting epithelial migration apically.

20 Claims, 4 Drawing Sheets



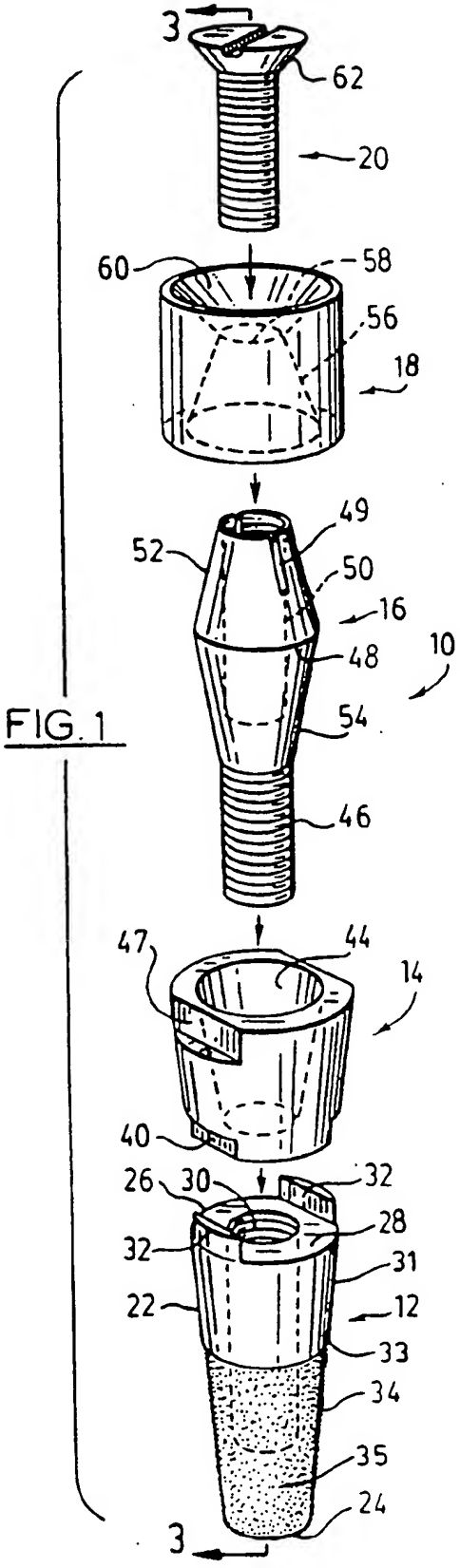

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FIG. 1

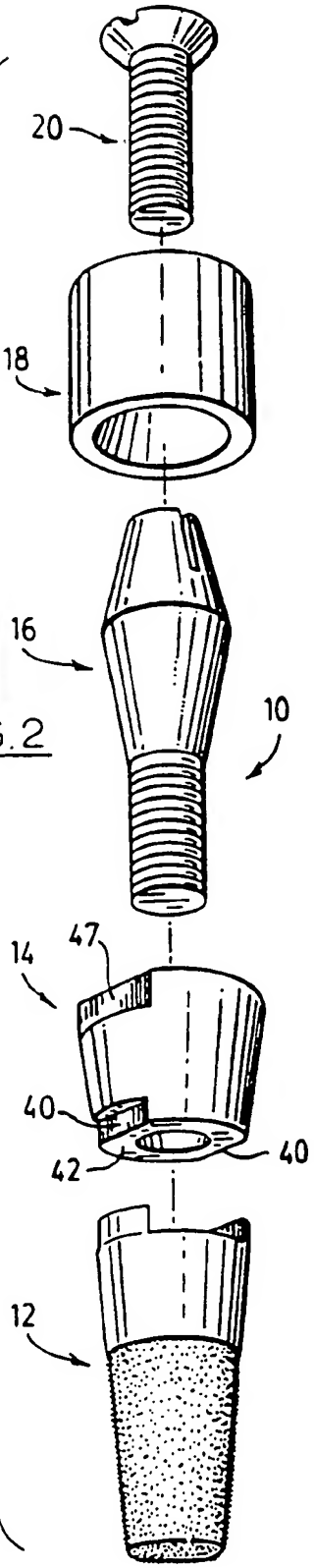
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FIG. 2

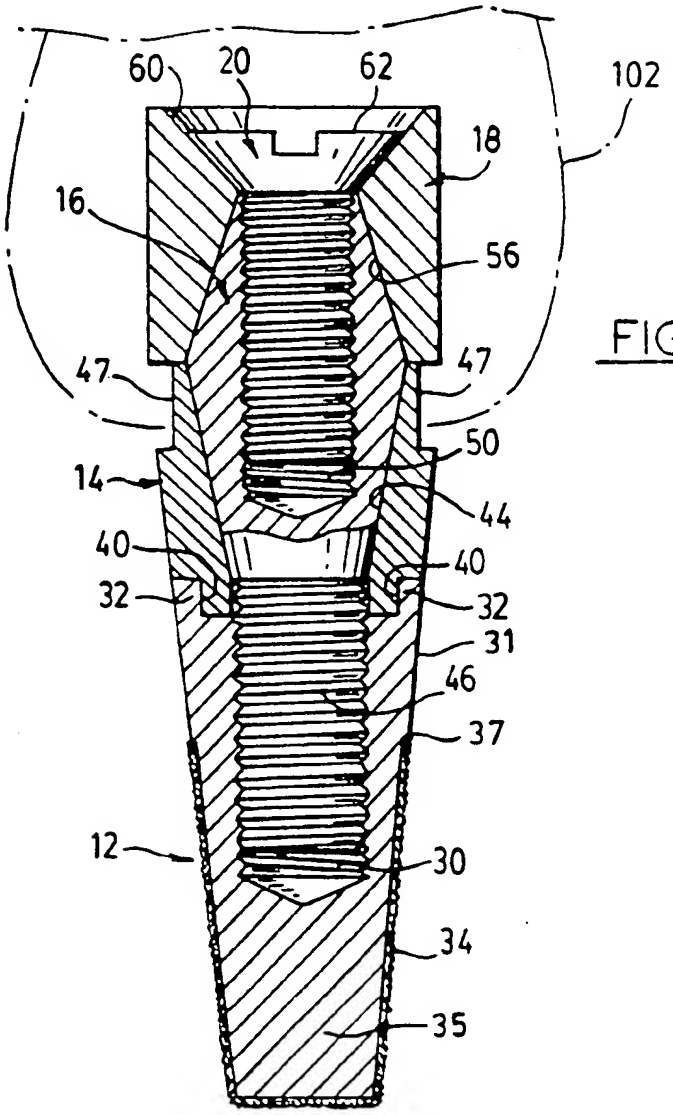
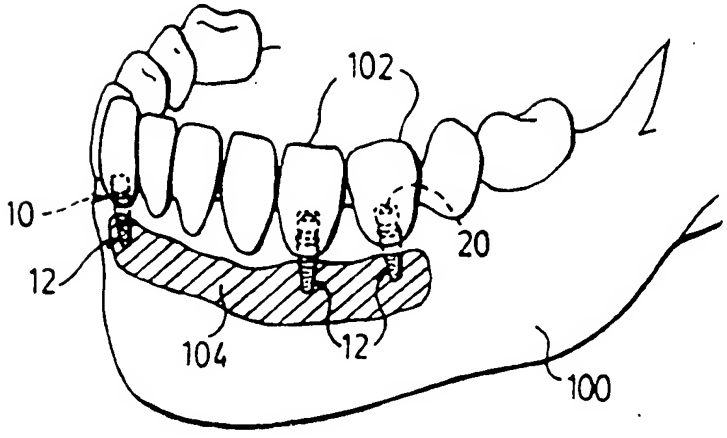
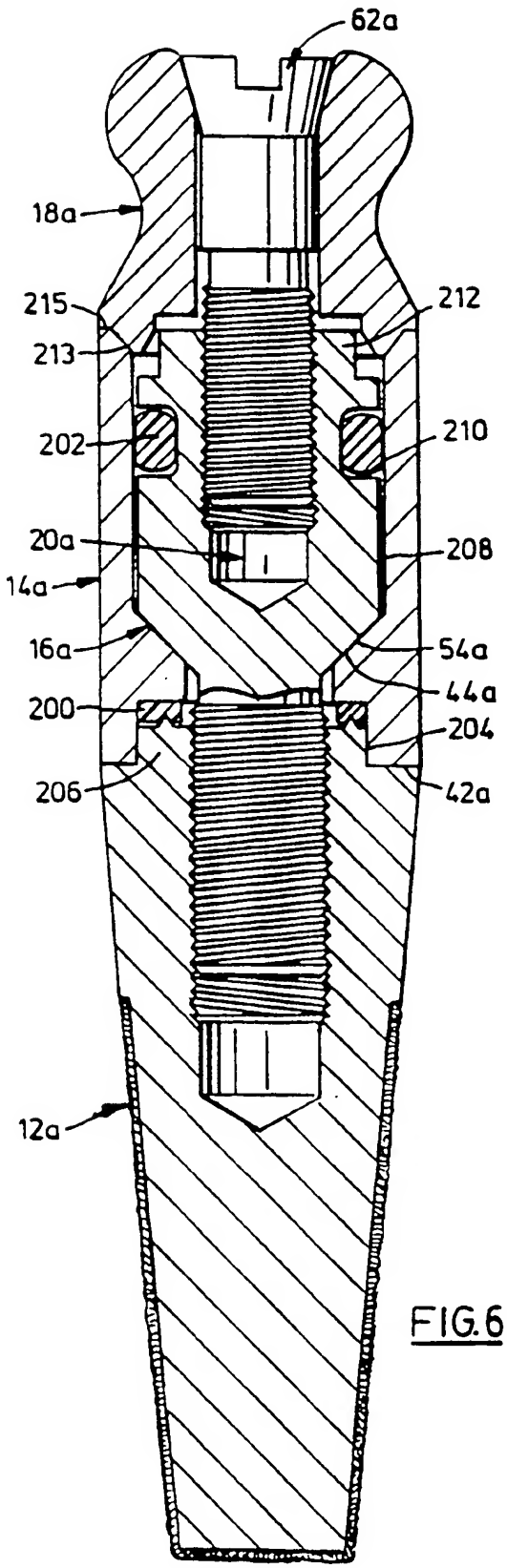


FIG. 3

FIG. 4

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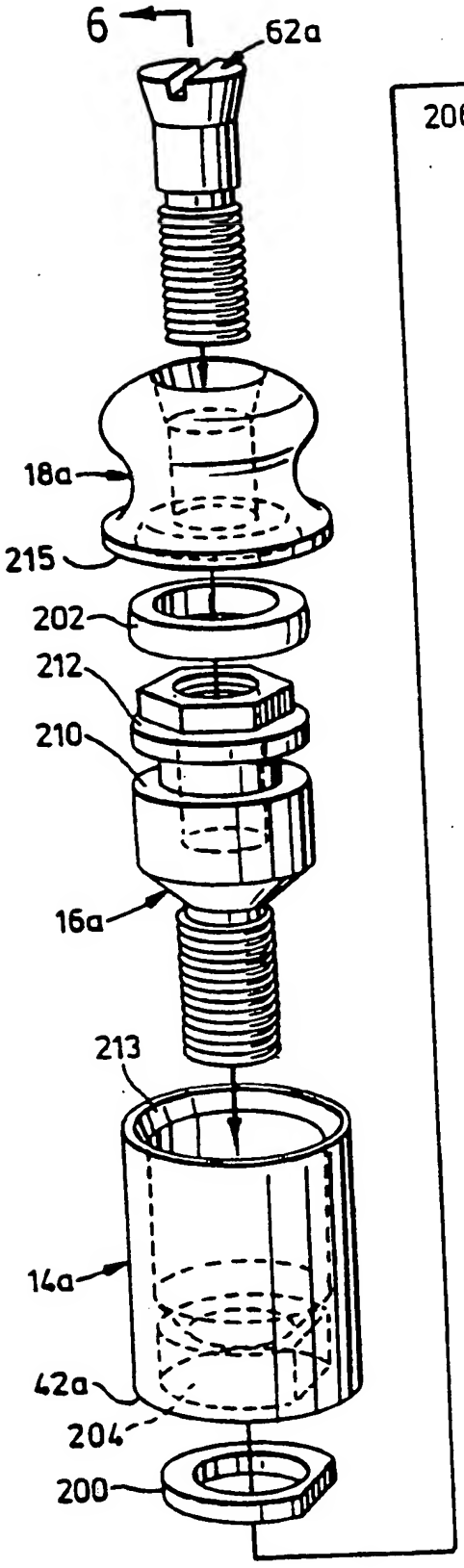
12a

FIG.6



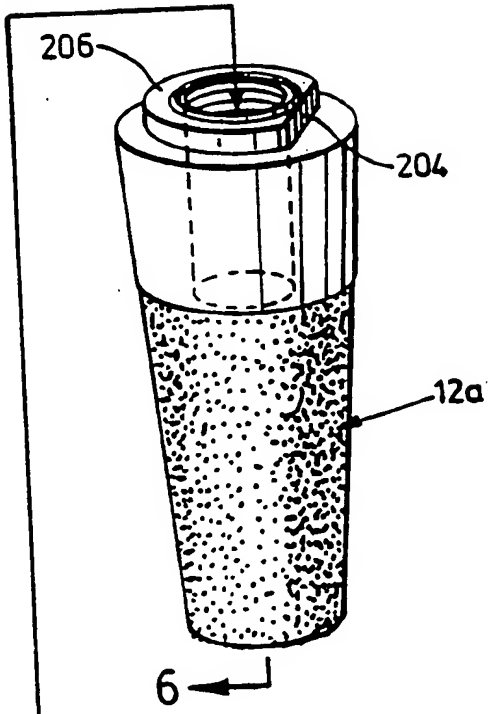


FIG. 5

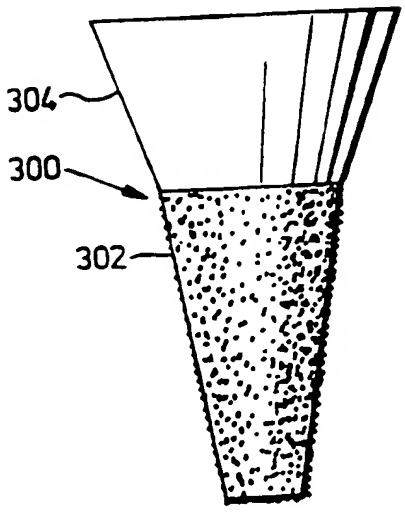


FIG. 7

POROUS SURFACED IMPLANT

This application is a continuation application of application Ser. No. 07/649,700, filed Feb. 1, 1991, now abandoned, which is a continuation-in-part of application Ser. No. 07/517,517, filed Apr. 26, 1990, now abandoned, which is a continuation of application Ser. No. 07/420,689, filed Oct. 11, 1989, now abandoned, which is a continuation of application Ser. No. 07/138,340, filed Dec. 28, 1987, now abandoned, which is a continuation-in-part of application Ser. No. 06/864,805, filed May 19, 1986, now abandoned.

FIELD OF THE INVENTION

The present invention relates to prosthesis and, more particularly, to means for connecting prostheses to bone.

BACKGROUND OF THE INVENTION

Devices of the type described herein serve generally to couple mechanically percutaneous prosthetic members for attachment of artificial eyes, ears, limbs, and, in particular, teeth to bone. Typically, such devices comprise two connectable main components; an implant component for integration with bone which serves an anchoring function and a separate support component that traverses epithelial tissue to which the prosthesis may be attached and subsequently coupled to the implant.

The tenacity with which the bone is able to retain the implant in situ is one factor which determines the success of devices of this type. This factor depends on the stability of the implant relative to the bone during the early healing phase following implant insertion and on the transfer of a small amount of stress from the implant to the bone in order to maintain bone and to increase bone density and strength.

Prior art proposals focus largely therefore on the means by which the implant is anchored within the bone.

One such proposal relating specifically to dental prostheses is disclosed in *Int. J. Oral Surg.* 1981; 10; 387–416, Adell et at. In that arrangement, screw-threaded cylindrical implants are provided upon which a dental bridge may be connected through a plurality of connectable supporting elements. Cooperation between the implant and the bone is provided by a bore in the jaw which is tapped to provide screw-threading complementary to the implant. A similar arrangement is proposed by Niznick in *Implantology,* November, 1983 Volume 73, Number 11, pages 13–15 in which the threaded cylindrical implant is provided near its base with channels through which bone is permitted to grow in order to enhance co-operation between the bone and the implant.

Another means by which an implant may be anchored in position is taught by Pilliar in U.S. Pat. No. 3,855,638. This reference describes a surgical prosthetic device with a porous metal coating. The dental implant taught by Pilliar comprises a cylindrical red having a porous coating on at least the areas of the implant in contact with and adjacent to bone. Such a porous coating allows for tissue ingrowth and tissue ossification. This reference suggests that the implant may also have a porous coating on the entire surface of the implant to encourage soft tissue growth in regions contacting such soft tissue. The provision of a porous coating on the entire implant surface provides, it is stated, a very rigid structure.

Further, in U.S. Pat. No. 4,223,412, Aoyagi et al. teach an implant having dental application comprising a pair of arms which extend into the receiving implant cavity. The entire surface of the implant is coated with a mixture of ceramics and hydroxyapatite, a mixture which has been shown to have excellent compatibility with living tissues. Such a coating has affinity to living tissue which allows for fixation of the implant.

Tapered implant devices are known. Greenfield (U.S. Pat. No. 943,113) provides a tapered implant frame for an artificial tooth. This design comprises a ribbed frame to allow for bone growth around and throughout the frame in order to secure the implant in position. Kiernan et al. (U.S. Pat. No. 2,857,670) also disclose a tapered implant for dental application. The way in which this implant is anchored in position, however, is by means of a plurality of serrations to allow bone growth throughout the implant. Outwardly extending studs are also provided on the implant for the purpose of gripping the surrounding bone structure.

Spector et al., in U.S. Pat. No. 4,164,794, disclose prosthetic devices having dental application. Specifically, there is disclosed a device having a tapered body, the entire surface of which is coated with a porous coating. However, it has recently been shown by Deporter et al. (J. Dent. Res. 67, 1190–1195, 1988) that the risk of infection from dental plaque may be increased when the entire length of the root component of such an implant is porous-coated. This risk is particularly increased when regions of the porous coating become directly exposed to the oral cavity.

It would be desirable to have an implant which, in use, possesses optimum fixation between the implant and the bone together with a reduced probability of the occurrence of infection.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a novel implant useful to connect prostheses to bone and which mitigates at least one of the disadvantages of prior implants.

Thus, according to one aspect of the present invention, there is provided an implant for insertion into bone through an epithelial and fibrous connective tissue layer adapted for connection of a prosthesis thereto, comprising:

a top portion for supporting a mechanical component to which a prosthesis may be connected; and

a body comprising an upper bone-attachment region tapering to a lower bone-engagement region having a porous surface,

wherein the upper bone-attachment region comprises a substantially non-porous surface and is capable of enhancing bone attachment thereto.

According to another aspect of the present invention, there is provided a device for connecting prosthesis to bone comprising:

an implant having a top portion for supporting a mechanical component to which a prosthesis may be connected, and a body comprising an upper bone-attachment region tapering to a lower bone-engagement region having a porous surface, the upper bone-attachment region comprising a substantially non-porous surface and being capable of enhancing bone attachment thereto; and

a mechanical component for connection to a prosthesis, the mechanical component comprising a collar, connecting means for connecting the collar to the implant, a coping for integration with the prosthesis, and retaining means for connecting the coping to the connecting means.

The combination in an implant of a tapered body having two surfaces, specifically a lower or apical porous surface for primary fixation of the implant (bone-engagement) and an upper or coronal surface which promotes the maintenance of bone surrounding this surface of the implant (bone-attachment), provides unexpected and surprising advantages over implants described in the prior art.

The tapered shape of the body of the implant is beneficial, particularly in the case of dental implants, since it provides a self-seating structure. Specifically, many implants, such as dental implants, are exposed to constant or regular compressive forces. The conical shape of the present implant minimizes apical movement of the implant providing stability which encourages bone ingrowth in the lower bone-engagement region of the implant body.

A porous coating on the surface of the lower bone-engagement region of the implant body provides for primary fixation of the implant to the bone as it allows for bone ingrowth to the porous coating. The porous coating has been found to provide a desirable degree of engagement between implant and bone without the need for threading of the bone which requires specialized skills and equipment.

It has also been found that the fixating property of such a porous coating is most effective if early movement of the implant is minimized or prevented. In the present case, such early movement is minimized or prevented by the tapered geometry of the body of the implant. Thus, the implant of the present invention provides means by which more secure anchorage of the implant within a receiving cavity is achieved.

The porous surface on the lower bone-engagement region of the implant body may be in the form of a coating comprised of discrete particles adhered to the implant surface into which bone may grow thereby fixing the implant and providing long term stability. Preferably, the porous surface comprises a porosity of from about 10 microns to about 800 microns. More preferably, the porosity of the porous surface is from about 50 to about 400 microns. Porosity ranges stated herein are defined by pore size.

In a preferred aspect of the present invention, interstitial bone growth may be enhanced by application of a protein coating over the porous surface of the lower bone-engagement region of the implant body. Such a protein coating may comprise a protein such as collagen.

The upper bone-attachment region of the implant body comprises a substantially non-porous surface. Thus, the surface of this upper region of the implant body is relatively smooth in comparison to the porous surface of the lower bone-engagement region. Preferably, the surface of the upper region is such that it has a porosity of not more than about 5 microns root mean square average (a surface with a porosity of about 5 microns root mean square average has the texture of a slightly roughened surface). It will be appreciated that a substantially smooth surface is included within this definition.

Preferably, the upper bone-attachment region of the implant body has a surface coated with a bioreactive material. The exact nature of the bioreactive material is not particularly restricted and may be a hydroxyapatite such as calcium hydroxyapatite. Such a coating is advantageous in that it provides an osteoconductive surface which promotes bone formation, attachment and retention as high as possible on the implant. Another feature of such a bioreactive coating is the provision of a smooth surface which is effective in preventing entrapment of bacteria. Specifically, it has been surprisingly and unexpectedly discovered that such a surface encourages bone formation and retention as high as possible on the implant body resulting in attachment of the bone to the upper surface. This provides secondary fixation of the implant within the bone cavity and minimizes the depth of gingival pockets which may form around the implant.

While not wishing to be bound by a specific scientific theory or mode of action, it is believed that bone growth is stimulated by a constant small amount of stress acting on the bone by a "foreign" object. In the absence of such stress, the bone may resorb which can cause formation of gingival pockets increasing the risk of infection. It is believed that the combination of a tapered implant body with the upper bone-attachment region discussed above assists in mitigating the occurrence of gingival pocket formation. The tapered shape provides effective transfer of stress to surrounding bone during occlusal function in comparison to the stress provided by a cylindrical implant. This may be due to the fact that application of a vertical force on a tapered implant results in two force components acting on bone surrounding the implant, specifically a normal force component and a shear force component. Effective transfer of stress enhances bone density and formation in the region of the implant. The provision of the upper bone-attachment surface discussed above provides the creation of a seal between the implant and the bone which serves to prevent substantially the development of gingival tissue invagination and the subsequent occurrence of implant failure or bacterial infection leading to various forms of gum disease.

BRIEF DESCRIPTION OF THE DRAWINGS

A preferred embodiment of the invention, particularly in respect of its application with dental prostheses, is hereinafter described by way of example only with reference to the accompanying drawings in which:

FIG. 1 is a perspective exploded view of a dental implant device showing individual components as viewed at an angle from above;

FIG. 2 is another exploded view of the same device shown in FIG. 1 at an angle from below;

FIG. 3 is a sectional view along line 3—3 of FIG. 1 with parts in assembled condition;

FIG. 4 is a perspective view of a series of devices in position on the jaw and supporting a dental bridge;

FIG. 5 is an exploded perspective view of another dental implant from above;

FIG. 6 is a sectional view along line 6—6 of the implant of FIG. 5; and

FIG. 7 is a side view of an alternative implant.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

Referring now to FIGS. 1 and 2, there is illustrated a device 10 comprised of an implant 12, a collar 14, a

connecting screw 16, a coping 18 and a retaining screw 20 all of which are preferably formed from a titanium alloy including aluminum and vanadium. Pure titanium and other biocompatible materials known in the art may also be used.

Implant 12, which is to be integrated with bone, has a tapered body 22 of frusto-conical shape delimited by a base 24 and a top 26. Top 26 of the implant 12 defines a planar surface 28 from which a screw-threaded bore 30 extends vertically into but not through the tapered body 22. The planar surface 28 is bordered by a pair of projections 32, diametrically opposed, which serve as interlocking elements for engagement with complementary formations on the undersurface of the collar 14.

Implant 12 comprises an upper bone-attachment region 33 having an outer surface 31 which is substantially non-porous. This smooth upper portion extends over about 2 mm of the uppermost length of the implant.

Implant 12 also comprises a lower bone-engagement region 35, including the base 24, provided with a porous surface 34 comprised of a network of discrete particles. The porous surface 34 provides interstices into which bone is permitted to grow once implant 12 is accommodated within the bone (FIG. 4). The discrete particles of porous surface 34 are preferably formed from the same titanium alloy from which implant 12 is formed, although other non-biodegradable, non-toxic, tissue-compatible materials may be used which admit of adherence to the material from which the implant is formed. Examples of such other materials include cobalt-chromium beads, hydroxyapatite, aluminum oxide and ceramic materials known in the art.

In a particularly preferred method of applying the porous coating, the desired material is powdered to provide spherical or irregularly shaped particles which are then admixed with adhesive and applied as a composition to the implant. The implant is then subjected to high temperature sintering, under vacuum, by which the adhesive is removed and the particles fused to the surface and to one another to form an interstitial matrix. The particles can vary from single layer to multilayer thickness. To accommodate the thickness of the particles deposited so that the surfaces of both upper bone-attachment region 33 and the lower bone-engagement region of the implant remain continuous, the porous coated region of the solid implant core is preferably stepped as shown in FIG. 3 at 37. By maintaining the porous coated region flush with the non-porous coated region of the implant, the sides of the implant will make intimate contact with the walls of the tapered bore in the jaw at the time of surgical placement.

The porous layer is provided to encourage growth of new bone into the interstices provided by the layer which growth provides for the anchoring function of the implant. Accordingly, the porosity of the layer is preferably controlled to within limits which, on one hand, allow influx of growing bone to a great extent and which, on the other hand, provide at least a minimum of surface to which the bone may anchor. It has been found that more preferred porosity ranges are on the order of from about 50 to about 400 microns although preferred porosities in the range of from about 10 to about 800 microns can be used. Successful results have been obtained using a porous layer derived from discrete particles of titanium-aluminum-vanadium having a porosity of from 50 to 400 microns for bone ingrowth and as low as 20 for connective tissue ingrowth. Also, the thickness of the porous layer may be varied provided preferably that the outer surface of the porous coating of the lower bone-engagement region remains flush with the upper bone-attachment region of the implant. Preferably, the thickness of the porous layer for materials made of titanium alloy is in the range of from about 20 to about 1,000 microns. The appropriate thickness of the porous layer deposited on a variety of other materials may vary depending upon the characteristic porosity of the deposited layer.

Collar 14 is adapted to be coupled to implant 12 in such a manner that rotation between the two components is precluded. This is accomplished by providing recesses 40 on the lower surface 42 of collar 14 which complement the projections 32 of implant 12. The collar defines a frusto-conically shaped bore 44 (FIG. 3) extending through its length allowing a screw-threaded shaft 46 of connecting screw 16 to be threadably engaged with a bore 30 of implant 12 so as to trap the collar 14 in position. Movement of the collar 14 in a vertical direction is restricted by an enlarged head 48 of the connecting screw and, particularly, by the nesting of a tapered lower portion 54 of the screw head within a complementary-shaped recess 44 of the collar 14, once screw shaft 46 is fully engaged within the implant 12. Since the torque applied to the connecting screw, when driving it into engagement with the collar 14, may be translated to the implant 12 if done forcefully, the collar 14 is provided with opposed parallel edges 47 for engagement with a suitable wrench. The torque applied while driving the connecting screw 16 can thus be countered by the wrench rather than by the implant 12, leaving the implant relatively undisturbed and anchored in the bone. To assist in driving of screw 16, the head of the screw is provided with a slot 49 for engagement by a suitable driver.

Head 48 of connecting screw 16 defines a screw-threaded bore 50 extending vertically into but not through connecting screw 16. An upper surface 52 of the connecting screw 16 is tapered so as to complement a correspondingly shaped recess 56 defined by coping 18. When properly aligned, a hole 58 in the top of a concave surface 60 of coping 18 aligns with screw-threaded bore 50 of connecting screw 16 so as threadably to engage a retaining screw 20 and trap coping 18 in position over the connecting screw 16. Concave upper surface 60 of coping 18 seats the head 62 of the retaining screw 20.

Advantageous features of the present invention may be realized in practice. In order to couple a dental prosthesis to bone, according to the preferred embodiment of the present invention, a bone 104 (FIG. 4) is drilled to define a bore of substantially the same contour as that of the implant. Thereafter, the implant is positioned in the bore, capped with a temporary cover (not shown) and left relatively undisturbed during a healing period. During the healing period, the bone surrounding the implant grows into the interstices in the porous layer of the lower bone-engaging region of the implant, thereby anchoring the implant in position and providing long term stability. Further, bone abuts against and attaches to the upper bone-attachment region of the implant.

After the healing period, the gingiva above the implant is opened, the temporary cap is removed and the collar, connecting screw, coping and retaining screw are accurately positioned on the implant. Thereafter, a cast is taken of the target region, i.e. the crestal region of the entire lower jaw 100 depicted in FIG. 4 including devices 10, and the cast is translated into a metal cast

framework supporting acrylic or porcelain teeth 102. Copings 18 are detached from each implanted device and incorporated into the bridge at positions corresponding exactly to the positions of the implants 12. The teeth of the completed dental bridge are provided with holes, each of which align accurately with the coping holes and which in turn align the threaded bore defined by the connecting screw. To secure the dental bridge 102 in position, retaining screw 20 is threadably engaged with the connecting screw bore so as to trap the coping and the dental bridge, within which the coping has been integrated, into position.

A healing cap 62 is provided to be placed at the time of implant insertion. This element serves to prevent tissue growth within the threaded portion of the implant component 12.

A similar process is employed where only a single artificial tooth is to be coupled. In this case, the artificial tooth is fashioned specifically to envelop the coping to ensure that it is properly integrated. The porous surface of the lower bone-engagement region is particularly advantageous when used for a single tooth since it will resist torsional movement of the implant better than a screw threaded design.

Another embodiment of the invention is shown in FIGS. 5 and 6. Elements similar to those in FIGS. 1–4 have been given the same reference numeral followed by the suffix "A".

Generally, this embodiment is of similar construction to that of FIGS. 1–4, with a few exceptions. In this embodiment, seals 200, 202 are provided between implant 12A and collar 14A and between connecting screw 16A and collar 14A, respectively, to inhibit seepage of oral fluids into the device which may cause infection.

In addition, connecting screw 16A has a shorter tapered lower portion 54A to reduce the amount of friction between this portion and the complementary shaped recess 44A in collar 14A.

In the central portion 208 of collar 14A, connecting screw 16A is generally cylindrical and has an annular recess 210 for housing a seal 202. Above this recess is an upper hexagonal portion 212 provided for engagement by a wrench to apply torque to drive the connecting screw 16A.

At its lower surface 42A, the collar has a part-circular recess 204 which fits over a complementary-shaped protrusion 206 in implant 12A. The interconnection of recess 204 and protrusion 206 inhibits relative rotational movement of implant 12A and collar 14A.

The upper surface 213 of collar 14A and a lower surface 215 of coping 18A are each provided with mating tapered portions to inhibit relative movement therebetween.

FIG. 7 is an alternative embodiment of an implant 300. In this embodiment, the implant 300 has a tapered lower bone-engagement region 302 having a porous coating and a tapered upper bone-attachment region 304 having a substantially non-porous surface. The taper angle of region 304 is greater than that of region 302 to provide additional protection against bone resorption which may occur in the region of the upper portion and to encourage bone formation in this region. In this embodiment, the lower bone-engaging region preferably has a taper angle of 5° (this angle can be up to 15°) and the upper bone-attachment region preferably has a taper angle of up to 30°.

By providing an implant having a tapered body, the present invention mitigates the disadvantages attendant with cylindrical implants known in the art. The tapered design of the implant provides for a stable initial friction fit between the bone and the implant. Subsequently, the close apposition of bone to porous coating and the transfer of stress to the apposed bone will encourage bone ingrowth and remodelling to effect sturdy attachment of implant to bone.

As a further desirable procedure of enhancing bone growth into the porous coating of the implant, the present invention contemplates use of a protein precoat over the porous layer of the lower bone-engagement region of the implant. It is believed that bone cells may be attracted by appropriate protein precoatings, allowing migration to occur more deeply and more rapidly into the interstices. Suitable protein precoats include collagen, fibronectin and platelet-derived growth factor on bone morphogenic protein. Precoating of the protein may be conducted using simple dipping techniques, generally known in the art. Hydroxyapatite or other calcium phosphate such as β-whitlockite may also be used as a precoating applied by plasma spraying, sputtering or other techniques generally known in the art.

Generally, the means by which a prosthesis may be attached to the implant may assume any number of configurations, subject to certain preferred criteria, so that the skilled artisan will appreciate that such implant may be adapted so as to couple to mechanical components other than that which is illustrated herein.

Important to the success of components for connecting a prosthesis to the implant, while not necessarily essential thereto, is the capacity of the connecting components to be detachable from the implant to allow the implant to be undisturbed during the healing period. Also, provision of a collar provides a means for connecting the coping, which is integrated with the prosthesis, to the implant which is integrated with the bone. To prevent rotation of the collar about the implant, a mechanical interlock should be provided at the interface of these two components and may also be provided between the collar/coping interface. Also, it is desirable to connect all of the components in such a manner as to prevent separation thereof in the vertical direction. Consideration also is given to the desirability of making the assembled fixture as streamlined as possible to prevent microbial flora from becoming established within pockets which might otherwise exist.

Moreover, it will be appreciated that the implant of the present invention is useful in anchoring prostheses other than dental prosthesis to bone. Such prostheses as eyes, ears and limbs may be coupled at the appropriate location using an implant of the type described herein together with the coupling components. Variation of specific design parameters may be required for example, where attachment to the comparatively thin cranium is required.

An embodiment of the present invention will now be exemplified by reference to the following non-limiting example.

PREPARATION OF THE IMPLANTS

Two different implant root designs fabricated from the titanium (Ti) alloy, Ti-6Al-4V (ASTMF 167), were used in this study.

The first design was identical to that previously reported (Deporter et al., *J. Dent. Res.*, 69, 1138–1145, 1990) except that the small vertical "step" previously

used to mechanically interlock the implant and collar was replaced with an internal hexagonal receptacle designed to receive a corresponding male insert located on the apical aspect of the collar. The root component consisted of a truncated conical shape (taper angle=5°). The apical two-thirds of the root component (the lower bone-engagement region) of which had a porous-surface coating formed by sintering two to three layers of Ti-6Al-4V alloy particles (diameter 45 to 150 μm) on the Ti alloy implant substrate. The coronal one-third of the root component (the upper bone-attachment region) had a machined alloy surface with a surface finish less than 1.75 microns cla (center line average).

The second design differed only in that the coronal one-third was 3.465 mm in diameter (versus 3.500 mm for the non-hydroxyapatite-coated implants of the first design) and was roughened by sandblasting to give a 4.5 to 5.0 micron Ra (root mean square average) surface roughness (as measured with a Taylor-Hobson profilometer) in preparation for subsequent plasma spray coating with hydroxyapatite (HA). This roughened surface was ultrasonically cleaned and plasma dried (in air). The hydroxyapatite powder used had a particle size of less than 125 microns. The plasma spraying conditions used are summarized in Table 1. Plasma spray coating resulted in nominally the same overall diameter as the uncoated design (3.50 mm), although some variation resulted because of the irregularity of the plasma-sprayed layer.

TABLE 1

Plasma Spraying Conditions	
Equipment:	Metco MN
Particle Size Range:	1–125 μm
Arc current:	400 A
Arc voltage:	60 V
Arc gas:	Nitrogen
Powder gas:	Nitrogen
Gun-Substrate distance:	8 cm
Gun-Speed:	10 cm/s
Powder flow rate:	10–15 g/min.
Substrate Cooling:	By air

The other components of the two implant systems were identical. As before all components of the implant systems were made by machining (Strite Industries, Cambridge, Ontario) while implant root components were porous-coated using methods previously described by Pilliar in *J. Biomed. Mater. Res.*, 21A, 1–33, 1987.

All implant components except the HA-coated root components were cleaned under sonication in the following sequential steps: (i) washing in 2% Decon (BDH chemicals) for 1 hour; (ii) three 3 minute washings in double-distilled, de-ionized water (DDDW); (iii) soaking in 28% nitric acid for 1 hour; and (iv) five 5 minute washings in DDDW. The cleaned implant components were then soaked for 1 hour in 100% ultrapure ethanol, air dried in a sterile air cabinet and autoclaved. In order to avoid possible dissolution of the hydroxyapatite coating, the HA-coated root components were washed only in DDDW three times successively for 15 minutes and were sterilized with dry heat for 40 minutes at 185° C.

FUNCTIONALITY OF THE IMPLANTS

Four male inbred beagle dogs (Laboratory Research Enterprises, Kalamazoo, Mich.) having initial weights of from 16 to 20 kg were used.

Implants were placed using a previously described (Deporter et al., *J. Dent. Res.*, 65:1064–1070, 1986) two-stage procedure in the regions of the mandibular third and fourth premolars which had been rendered edentulous six months prior to implantation. Two porous-coated implant root components without HA on the coronal third were placed on the left side and two porous-coated implant root components with HA coatings over this coronal region were placed on the right side of the mandible of each dog. After an initial healing period of six weeks, all root components were uncovered each to receive a collar and collar-retaining screw. Each pair of implants was then used to support a fixed bridge for an 18 month functional period during which the implants were cleaned thrice weekly using 0.2% chlorhexidine as previously described (Deporter et al., *J. Dent. Res.*, 65:1071–1077, 1986).

During the functional period each implant was examined radiographically every four weeks with the dogs under general anaesthesia starting at the time of bridge insertion (approximately one week following placement of the collar and collar-retaining screw). A custom-made film holder was used, similar to one previously developed for use in humans (Cox and Pharoah, *J. Prosthet. Dent.*, 56:338–341, 1986), to achieve greater standardization of radiographic geometry in successive radiographs of the same implant. At each monthly examination, bridges were removed and the film holder was connected to each implant individually. Kodak ultra-speed DF-57 radiographic films (sizes #1 or #2), all from the same batch, were exposed using a Heliodent 70 (Siemens) x-ray machine with exposure factors of 70 KVp, 8 mA, 22 impulses and focal-film distance of 39.5 cm (15.5 inches). All films were developed manually using freshly mixed Kodak GBX developer and fixer (cat. 190 1859).

All radiographs were analyzed as follows. Films were transverse-illuminated and projected (magnification factor—6.6×) onto a monitor using a video camera (DAGE-MTI Inc., Michigan City, Ind., model N70). The images were digitized using a two image digitizing board (MATROX Corp., Dorval, Quebec) mounted in a graphics-oriented computer (Silicon Graphics Inc., Mountainview, Calif., model IRIS 3120) and a customized computer program was used to measure the crestal bone height adjacent to each of the mesial and distal surfaces of each implant. These height measurements were calculated and expressed by the computer as a fraction of the vertical height of the porous-coated segment of the root implant component. Since the crestal bone height was usually coronal to the machined surface-porous surface junction, the majority of height measurements are greater than 1.00.

ANALYSIS OF RESULTS

Following the 18 month functional period, the subjects were euthanized. Segments of mandible containing the implants were removed, processed and embedded in methylmethacrylate, and sectioned for histological assessment (Deporter et al., 1986; 1988). The sectioning technique was such as to provide two buccolingual, two mesial and two distal sections of each implant. In some cases it was possible to obtain three sections in one plane, while in others it was possible to obtain only one because of technical complications. The sections were examined both qualitatively and using computer-assisted morphometry. For the latter, black and white photomicrographs of each section at 26.5× magnification were prepared and analyzed using a digitizing tab-

let and Bioquant System IV software package (R & M Biometrics Inc., Nashville).

For each of the coronal one-third (machined only or HA-coated) and the apical porous-coated two-thirds of each aspect (buccal vs. lingual vs. mesial vs. distal) of each implant, the absolute length of implant surface in apparent direct contact with bone was determined as shown in Table 2. These data are referred to as the S-Contact (smooth coronal $\frac{1}{3}$) and P-Contact (porous-coated apical $\frac{2}{3}$), and are expressed as both the as-measured absolute lengths (S-Contact, P-Contact) and as a fraction (S-Contact Length Fraction—S-CLF, and the P-Contact length fraction—P-CLF) of the maximum length of the respective (i.e. coronal $\frac{1}{3}$ or apical $\frac{2}{3}$) implant surface available for contact with bone. The CLF fraction is equal to the length of bone in contact with the implant surface/length of available implant surface.

TABLES 2 (a) and (b)

A comparison of the mesial and distal aspects of the coronal one third or upper bone-attachment region (a) and apical two-thirds or lower bone-engagement region (b) of the two implant designs on the basis of bone height, absolute contact length and contact length fraction.

(a) coronal one third (upper region)

	S-Height (mm)	S-Contact (mm)	S-CLF (%)
non-coated	0.77	0.61	30.12
coated	0.99	0.71	34.21
coated minus non-coated (±SE)	0.23 ±0.10	0.10 ±0.10	4.09 ±4.58

(b) apical two thirds (lower region)

	P-Height (mm)	P-Contact (mm)	P-CLF (%)
non-coated	2.70	4.31	46.83
coated*	2.73	3.59	40.06
coated minus non-coated (±SE)	0.04 ±0.20	−0.72 ±0.36	−6.77 ±3.55

*corresponding coronal one-third coated with HA

In addition, the straight line vertical heights of bone in contact with each of the coronal $\frac{1}{3}$ and apical $\frac{2}{3}$ of each aspect of each implant were determined as shown in Table 3. These are respectively referred to as the S-Height (coronal $\frac{1}{3}$) and the P-Height (for apical $\frac{2}{3}$). These latter measurements were made directly from the histological slides using a stereomicroscope at 20× magnification and a Vernier gauge (Mitutoyo Canada, Streetsville, Ontario).

TABLES 3 (a) and (b)

These tables display the adjusted mean for bone heights, absolute contact lengths and contact length fractions for the coronal one third (a) and porous-coated apical two thirds (b) for each of the buccal and lingual aspects of the two implant designs.

(a) coronal one third

	S-Height (mm)		S-Contact (mm)		S-CLF (%)	
	Buccal	Lingual	Buccal	Lingual	Buccal	Lingual
non-coated	0.78	0.78	0.65	0.57	31.9	28.4
coated	1.03	0.99	0.72	0.71	34.5	34.4
coated minus non-coated (±SE)	0.25 ±0.13	0.21 ±0.17	0.07 ±0.14	0.14 ±0.14	2.6 ±6.4	6.0 ±7.1

(b) apical two thirds

	P-Height (mm)		P-Contact (mm)		P-CLF (%)	
	Buccal	Lingual	Buccal	Lingual	Buccal	Lingual
non-coated	2.76	2.63	4.22	4.42	46.4	47.3
coated*	2.66	2.81	3.49	3.65	40.4	39.7
coated minus non-coated (±SE)	−0.11 ±0.29	0.17 ±0.32	−0.73 ±0.55	−0.76 ±0.53	−6.0 ±5.6	−7.6 ±5.2

*corresponding coronal one-third coated with HA.

Comparisons were made between the two implant designs controlling for variation among the dogs and possible positions, side and section of the implants, using analysis of variance. Computations were done using procedure GLM in the Statistical Analysis System to accommodate lack of balance (i.e. inequalities in the number of observations in all subcategories). Least square means were computed for observations made on the hydroxyapatite and control surfaces. These comparisons were carried out separately for the smooth and porous regions of each section of implant.

Finally, selected tissue-implant blocks that remained after sectioning for histological studies were completed, ground and polished using standard metallographic procedures in order to examine the HA coating after a prolonged in vivo exposure. For the specimen preparation, the final grinding and polishing directions were normal to the ceramic-metal interface with the grinding and polishing direction from the ceramic to the metal to avoid effects of metal smearing over the HA coating.

RESULTS

All of the implants became fixed by bone ingrowth and remained so throughout the 18 month functional period. The associated gingival tissues were in all cases keratinized and remained healthy in appearance.

The placement of a bioreactive hydroxyapatite plasma-sprayed coating over the smooth coronal region of the partially porous-coated dental implant results in bone retention to a greater height in this region. This is significant since loss of crestal bone adjacent to the non-coated implant generally results in periimplant pocket formation thereby increasing the susceptibility of an implant to plaque accumulation leading to tissue loss as well as infection.

What is claimed is:

1. An implant for insertion into bone through an epithelial and fibrous connective tissue layer and useful to connect a prosthesis thereto, the implant comprising:
   - a top portion for supporting a mechanical component to which a prosthesis may be connected; and
   - a body comprising an upper bone-attachment region tapering at an angle of about 5 degrees to a lower bone-engagement region formed from a material having a porous surface:
   - wherein said upper bone-attachment region comprises a substantially non-porous surface capable of enhancing bone attachment thereto.

2. The implant defined in claim 1, wherein said non-porous surface of said upper bone-attachment region comprises a bioreactive coating.

3. The implant defined in claim 2, wherein said coating is calcium hydroxyapatite.

4. The implant defined in claim 2, wherein said non-porous surface is a roughened surface having a porosity

of not more than about 5 microns root mean square average.

5. The implant defined in claim 4, wherein said nonporous surface is made of a titanium alloy.

6. The implant defined in claim 2, wherein said mechanical component is releasably retainable on said implant.

7. The implant defined in claim 2, wherein said upper bone-attachment region has a larger taper angle than said lower bone-engagement region.

8. The implant defined in claim 2, wherein said upper bone-attachment region is flush with said lower bone-engagement region.

9. The implant defined in claim 2, wherein the top portion of the implant defines engagement means for complementary engagement with said mechanical component to resist rotation of said mechanical component about said implant.

10. The implant defined in claim 2, wherein said porous surface has a porosity from about 50 to about 400 microns.

11. The implant defined in claim 1, wherein said porous surface has a porosity from about 10 to about 800 microns.

12. The implant defined in claim 1, wherein said porous surface is formed from discrete particles of the same material from which the implant is formed.

13. The implant defined in claim 1, wherein said porous surface is formed from a material selected from the group consisting of titanium alloy, cobalt-chromium, hydroxyapatite, aluminum oxide and ceramic material.

14. The implant defined in claim 13 wherein said protein is collagen.

15. The implant defined in claim 1, wherein protein is layered over said porous surface.

16. A device for connecting prosthesis to bone comprising:

an implant having a top portion for supporting a mechanical component to which a prosthesis may be connected, and a body comprising an upper bone-attachment region tapering at an angle of about 5 degrees to a lower bone-engagement region having a porous surface, the upper bone-attachment region comprising a substantially nonporous surface capable of enhancing bone attachment thereto; and

a mechanical component for connection to a prosthesis, the mechanical component comprising a collar, connecting means for connecting the collar to the implant, a coping for integration with said prosthesis, and retaining means for connecting the coping to said connecting means.

17. The device defined in claim 16, wherein the upper bone-attachment region of said implant has a greater taper angle than that of the lower bone-engagement region of said implant.

18. The device defined in claim 16, wherein the upper bone-attachment region of said implant has a bioreactive coating thereon.

19. The device defined in claim 18, wherein said coating is calcium hydroxyapatite.

20. The device defined in claim 16, wherein the surface of the upper bone-attachment region of said implant has a porosity of not greater than about 5 microns root mean square average.

* * * * *

United States Patent [19]

Gustilo

[11] **Patent Number: 4,463,753**

[45] **Date of Patent: Aug. 7, 1984**

[54] **COMPRESSION BONE SCREW**

[76] Inventor: **Ramon B. Gustilo**, 701 Park Ave., Minneapolis, Minn. 55415

[21] Appl. No.: **301,415**

[22] Filed: **Sep. 11, 1981**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 109,639, Jan. 4, 1980, abandoned.

[51] **Int. Cl.**[3] A61F 5/04

[52] **U.S. Cl.** ..... **128/92 B**; 128/92 BC; 128/92 BB

[58] **Field of Search** ..... 128/92 B, 92 BC, 92 BB, 128/92 R

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Attorney, Agent, or Firm—Sherman & Shalloway

[57] **ABSTRACT**

A compression screw having a proximal portion and a distal portion integrally interconnected by an intermediate tapering portion. The proximal and distal portions have threads of the same pitch. The intermediate portion has a smooth outer surface tapering the larger diameter proximal portion into the smaller diameter distal portion. The shaft of the proximal portion is cylindrical and the shaft of the distal portion is tapered, terminating in a sharp trocar point, and the threads of the proximal and distal portion may be provided with self-cutting flutes. The smooth tapering surface of the intermediate portion cooperates with the threads at the distal end to effect counteracting forces which cause compressions of the bone between the distal end and the taper.

13 Claims, 9 Drawing Figures

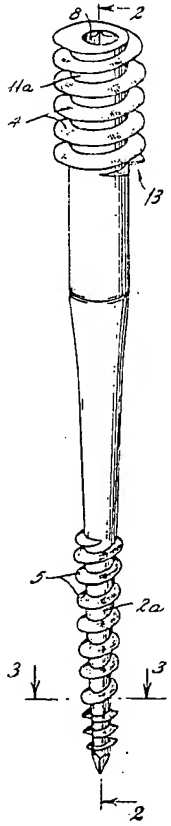


Fig. 1

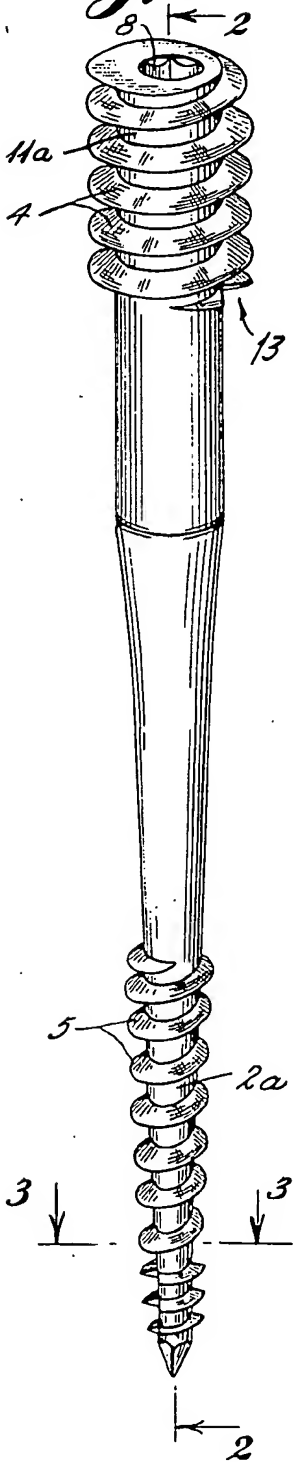


Fig. 2

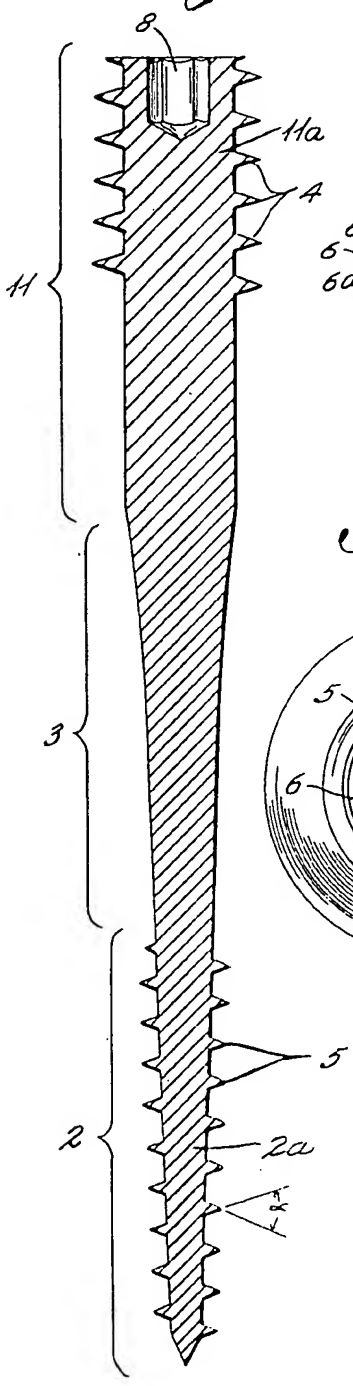


Fig. 3

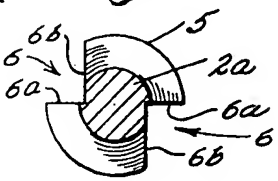


Fig. 4

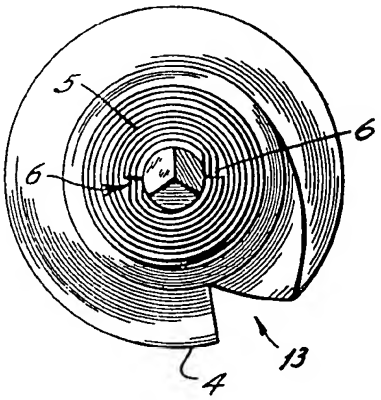


Fig. 5a

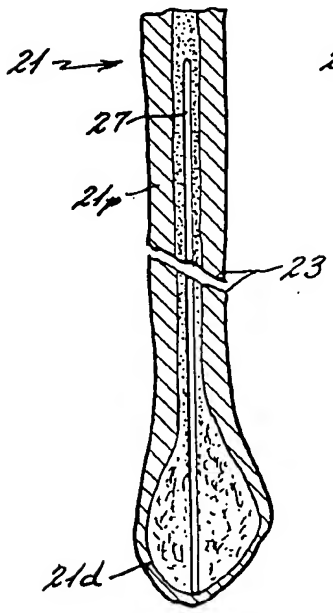


Fig. 5b

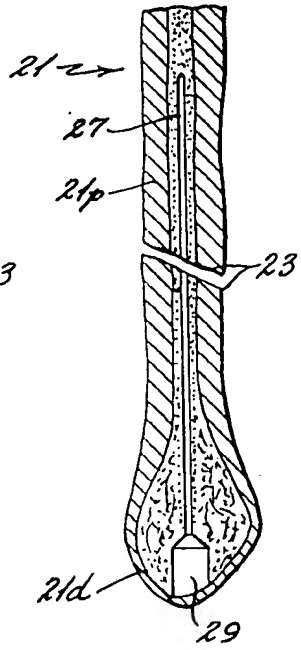


Fig. 5c

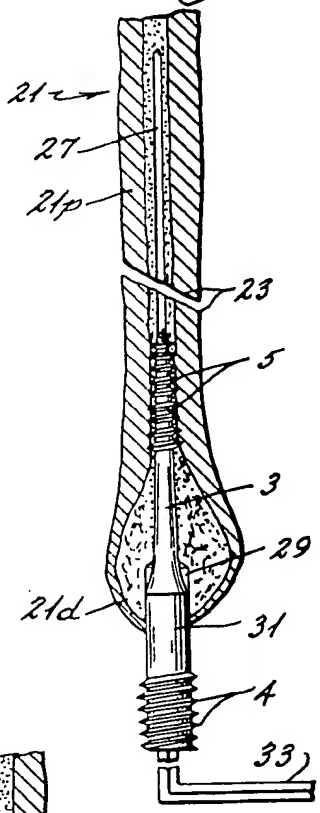


Fig. 5d

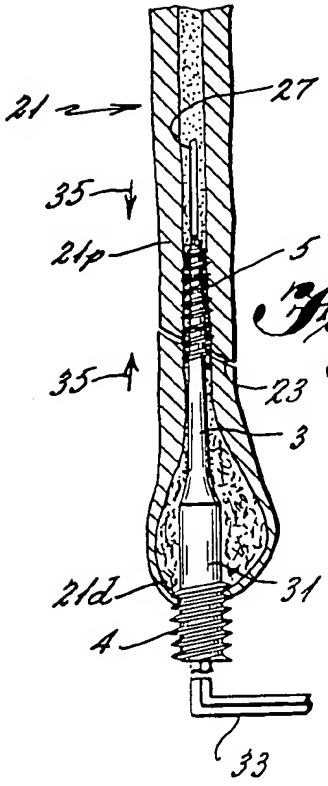
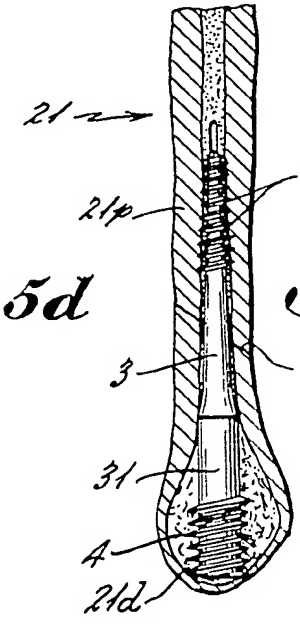


Fig. 5e



COMPRESSION BONE SCREW

This application is a continuation-in-part of Ser. No. 109,639, filed Jan. 4, 1980, now abandoned.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention generally relates to a screw for joining parts of bone.

Many types of bone fractures, particularly fractures of the fibula are lateral fractures occurring near the distal end of a long bone. In such a case, if reinforcement is necessary, it may be desired to provide such reinforcement parallel to the length of the bone. In particular, this invention is directed to the provision of reinforcement, with a compressive force, along the medullary canal of the long bone, with access to the medullary canal being achieved by drilling along the center of the bone from the end of the bone.

While most fractures of long bones are transverse fractures, such fractures usually do not occur along lines perpendicular to the length of the bone, but rather occur along fracture lines which cross the bone in a diagonal direction. Thus, direct compressive force in many cases tends to cause the segments of the bone to shift laterally, thus defeating the purpose of intentionally applied compressive force. For this reason, any device effecting longidutinal compression at a fracture site must also provide a means for aligning the two segments of the bone so as to avoid any lateral shift.

2. Description of the Prior Art

Many types of screws are known in the prior art. For example, Russell in U.S. Pat. No. 146,023 describes a wood screw with a thread of varying pitch gradually decreasing from the point of the screw.

Fracture screw adjusting means are also known in the prior art as described by Charnley in U.S. Pat. No. 2,801,631.

Anchoring arrangements for joining two dissimilar materials are disclosed in Canadian Pat. No. 731,381, issued to Fischer.

None of the above-disclosed attaching structures have been particularly applied to use as a distal fibular screw.

A screw described by Herbert in U.S. Pat. No. 4,175,555 has two threads, separately located at different locations along the length of the screw at distal and proximal ends, respectively, the threads being separated by a shank portion. The distal threaded portion has a diameter which is smaller than the proximal threaded portion, while the thread pitch of the (narrow) distal threaded portion is greater than the thread pitch of the (wide) proximal threaded portion. This thread pitch differential causes the distal end of the screw to attempt to advance through bone tissue for each clockwise turn of the screw at a rate greater than the rate of advance of the proximal end of the screw. The difference in advance rates results in the compression of bone at the distal end against bone at the proximal end. It can therefore be seen that Herbert effects a compression which changes in accordance with the number of turns that the screw is threaded when the proximal threads are engaging bone.

SUMMARY OF THE INVENTION

It is an object of the invention to describe a bone screw having a distal portion and a proximal portion integrally interconnected by an intermediate portion. It is a further object of this invention to describe a bone screw having distal threads and proximal threads of the same pitch. It is an object of this invention to describe a bone screw having distal and proximal threads having self-cutting flutes. It is another object of this invention to describe a bone screw terminating in a sharp trocar point. It is an object of the invention to describe a bone screw having an intermediate portion with a substantially smooth outer surface. It is another object of this invention to describe a bone screw, particularly a fibular screw, having a cylindrical proximal shaft tapering into a tapered distal shaft.

It is a further object to provide a means for repair of a fracture running transverse to, or diagonally transverse to, the length of a long bone in which the repair medium compresses the fractured segments of the bone parallel to the length of the bone while maintaining a lengthwise alignment of the bone. It is a further object to provide a means for repairing such a bone in such a manner in which a screw is inserted so that a portion of the screw runs along the medullary canal of the bone, with the path of the screw ensuring that the bone segments remain in axial alignment, and in which the screw effects a longitudinal compression of the bone segments. It is yet a further object to describe a fibular screw which accomplishes this kind of compression, and which can be additionally used for repairs of lung bones other than the fibula.

The bone screw according to the invention is comprised of a proximal portion having a cylindrical proximal shaft and proximal threads. The proximal threads may be provided with self-cutting flutes in the form of notches. The proximal portion is provided with a means for engaging a tool such as a hexagonal opening for engaging a hexagonal screw driver designed to fit allen screws. The proximal portion integrally terminates into an intermediate portion having a substantially smooth outer surface tapering and integrally terminating into a distal portion. The distal portion has a distal tapering shaft terminating in a trocar point. The distal portion is provided with distal threads having the same pitch as the proximal threads. The distal threads also may be further provided with self-cutting flutes in the form of notches.

The screw is used by drilling a fractured long bone, such as a fibula, from the end thereof. The bore is enlarged at the entry point to a diameter sufficient for the proximal end of the screw to enter the bone, with the proximal end engaging the bone. It is significant that a portion of the purchase site which is to be engaged by the tapering intermediate portion is drilled narrower than the tapering portion, at least before the fracture line of the bone is reached.

By the distal threads engaging the bone beyond the fracture line when the tapering part of the intermediate portion is engaging the bone before the fracture line, a compressive force between the segments of the bone on opposite sides of the fracture line is established. This compressive force is maintained at least until the proximal threads engage the bone, thus establishing a compressed relationship between the bone segments engaged by the proximal and distal ends of the screw. Thus, compression is achieved by the profile of the screw rather than a differential thread pitch. An axial alignment of the bone segments is established as a result of the screw engaging the bone along the drill bore.

BRIEF DESCRIPTION OF THE DRAWING

These features and object of the invention will become apparent to those skilled in the art by referring to the accompanying drawing in which:

FIG. 1 is a perspective view of the fibular screw according to the invention;

FIG. 2 is a longitudinal sectional view of the fibular screw according to the invention;

FIG. 3 is a sectional view taken along lines 3—3 of FIG. 1;

FIG. 4 is a distal end view of the fibular screw according to the invention; and,

FIGS. 5A-5E show a preferred technique for using the fibular screw according to the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

In order to more fully understand the invention, it should be pointed out that the words, "distal," and, "proximal," will be used to describe portions both of the screw and of the bone in the following manner:

When a fracture occurs at a portion of a long bone near an end of that bone furthest from the body, that fracture is said to occur at the distal, rather than the proximal end of the bone. On the other hand, the fibular screw will be described as being inserted in that end; the screw will be arranged so that the proximal end of the screw is adjacent the distal end of the bone. Therefore, the distal end of the screw will be the part of the screw that is closest to the proximal end of the bone. For this reason, the proximal and distal portions of the screw should not be confused with the proximal and distal ends of the bone, which are often, but not always, in opposite alignments.

The preferred form of the invention is shown as a distal fibular screw (i.e., a screw to be inserted into the distal end of the fibula) and includes a proximal portion **11**, a distal portion **2** and an intermediate portion **3** integrally interconnecting the proximal portion **11** and distal portion **2**. Preferably, the proximal portion **11** has a proximal shaft **11***a* which is cylindrical in shape. The proximal shaft **11***a* is provided with a plurality of proximal threads **4** having a given pitch.

The distal portion is comprised of a tapered distal shaft **2***a* terminating in a sharp trocar point **7**. The distal portion **2** is provided with a plurality of distal threads **5**. In the preferred embodiment, the distal threads may be provided with at least one self-cutting flute **6**. The flute is preferably a notch which cuts through the threads **5**, the notch having a wall **6***a* perpendicular to the distal shaft **2***a* and a wall **6***b* parallel to a tangent of the distal shaft **2***a*. The embodiment illustrated in FIGS. **1-4** utilize two such flutes **6** in the distal thread portion **2**.

The proximal portion **11** is provided with a means for engaging a tool such as hexagonal opening **8** for engaging a hexagonal wrench. The intermediate portion **3** is integral with the proximal portion **11** and distal portion **2**. The proximal portion **11** has a diameter which is greater than the greatest diameter of the distal portion. The proximal threads **4** may also include at least one self-cutting flute in the form of a notch **13** (FIGS. **1** and **4**) such as those described for the distal threads. A particularly advantageous embodiment may include three notches **13** in the proximal portion and two flutes **6** in the distal portion.

In the embodiment shown, the proximal threads **4** have the same pitch as the distal threads **5**. Regardless of the relative thread pitches, due to the tapered intermediate portion **3**, a certain amount of compression can occur as the tapered area wedges into the bone or the medullary canal. That is, as the screw is applied to the bone the continuously increasing diameter of the intermediate portion causes compression between bone engaged by the intermediate portion **3** and the bone engaged by the distal threads **5**. Preferably, the screw is threaded with relatively large threads, as illustrated to achieve substantial thread to bone contact. The screw is preferably made of a metal such as stainless steel.

Inasmuch as the tapered intermediate portion **3** is intended to effect compression, in the preferred embodiment, the intermediate portion **3** must be of sufficient length for at least a part of the intermediate portion **3** to engage the bone on one side of a fracture line while the distal threads **5** engage the bone at the other side of the fracture line. This would occur prior to the proximal threads **4** engaging the bone.

The tapered shaft **2***a* of the distal portion **2** is tapered slightly to conform to the narrow canal just above the lateral malleolus. The hexagonal opening **8** allows the proximal end of the screw to be engaged by a tool so that the screw can be recessed flush with the bone.

OPERATION AND SURGICAL PROCEDURE

Referring to FIGS. 5A-5E, a typical fracture **23** of the fibula **21** is shown. FIGS. 5A-5E illustrate a lateral view of the fibula. As is shown, fracture **23** will most likely occur along a fracture line near the distal end **25** of the bone, segmenting the fibula **21** into distal and proximal fragments **21***d* and **21***p*, respectively. In order to insert the screw, the distal end **25** is exposed by temporarily separating, to the extent necessary, the distal end **25** from the astragalus (not shown) and associated tendons and ligaments located at the distal end **25**. After exposure of the distal end **25**, the fibular is maintained in alignment and a center bore **27** is drilled along the length of the fibular **21** from the distal end. The bore **27** is sized so that the distal end of the bone screw will threadingly engage the bore. Preferably, the center bore **27** is drilled with a drill bit corresponding to the diameter of the leading tip end of the distal shaft **2***a*. The bore **27** is widened for a short distance from the distal end **25** in order to form a wider diameter portion **29** of the bore **27**. The wider diameter portion **29** is preferably drilled with a bit corresponding to the diameter of the proximal shaft **11***a*. This wider portion **29** permits engagement of the threads **4** at the proximal portion of the screw, while allowing the screw to penetrate the outer cortex of the bone as the screw enters the distal end **25** of the bone.

After the purchase site is cleared of thrombosi and other debris, the screw **31** is inserted into the center bore **27** by using an allen key **33** or similar tool. While the allen key **33** is shown for simplicity, it is anticipated that an allen screwdriver will actually be used as the turning tool. When the distal threads **5** of the screw **31** have substantially cleared the fracture line **23**, the taper at the intermediate portion **8** creates opposing forces, as indicated by arrows **35**. As the tool **33** is rotated, these forces can continue to develop until the proximal threads **4** hold the bone **21** in the state of compression so established.

Compression of the distal bone fragment **21***d* onto the proximal bone fragment **21***p* is achieved as the distal threads **5** engage the proximal bone fragment **21***p*, as insertion continues and as the diameter of the intermediate portion **3** tapers to the larger diameter of the proxi-

mal portion 1, forcing the distal fragment of bone 21*d* (compressing the fracture) onto the proximal fragment 21*p*, pushing the distal portion 21*d* ahead. The compression takes place before the proximal threads 4 enter the bone 21.

Since, in the preferred embodiment, both sets of threads 4, 5 are of same pitch, as both sets of threads become engaged in the bone 21, no further compression is achieved because threads of the same pitch would be advancing the same amount. This is important because the engagement of the proximal threads 4 with the distal bone fragment 21*d* fixes the amount of bone compression established.

It should be clear that, although the compressive force may later subside as the bone tissue releases pressure against the distal threads 5 and the intermediate portion 3, the engagement of the proximal and distal threads 4, 5 with the bone 21 still provides a fixed relationship for the bone on either side of the fracture line 23. It should be further noted that, since the bore 27 and consequently the distal portion 2 of the screw 31 coincide with the medullary canal, a minimum of structural bone is lost in the narrow portion. This minimization of structural loss provides an increased strength of the bone 21 adjacent the distal portion 2 of the screw 31, that being the portion of the bone 21 where the reinforcement terminates and inherent bone strength is most needed.

While the placement of the proximal end 11 of the screw is mostly or entirely within cancellous bone, the distal end 2 is primarly placed in the cortical bone surrounding the medullary canal. Since the distal end 2 exerts a significant force on both the intermediate portion 3 and on the proximal end 11 of the screw, the included angle α of the thread cross-sections is critical. If that included angle α is less than 20°, than the threads have a reduced strength which would result in the threads collapsing, this being primarily a problem with the distal threads 5. If the included cross-sectional angles α is too great, the threads have a reduced purchasing power and would therefore have a tendency to "strip out" of both the cortical bone engaged by the distal threads and the cancellous bone engaged by the proximal threads. For this reason, the included angle α must be less than 60°. In the preferred embodiment, the included cross-sectional angle α is 40° which is within a preferred range of between 30° and 50°. Thus, the threads 5 at the distal end 2 are able to "grab" the cortical bone at the medullary wall, threads 4 at the proximal end 11 are able to maintain a satisfactory grip on the cancellous bone occuring at the distal end of the fibula. Thus, the proximal and distal threads 4, 5 are "cut" within the same included cross-sectional angle α and with the same pitch as described above.

It is contemplated that the screw may be supplied in different sizes. Generally, 90% of all fibular fractures occur just above the lateral malleolus (distal fibula) where the fibula "necks down". Often these fractures are comminuted. In the past, rush rods have been used, but these rods tend to rotate and back out. The disclosed fibular screw avoids this drawback by providing proximal and distal threads of the same pitch.

Various changes may be made in the details of the invention, as disclosed, without sacrificing the advantages thereof or departing from the scope of the appended claims. Furthermore, although the present invention has been disclosed and discussed with regard to its exceptional advantages in terms of a fibular screw, it may be understood that the invention may be employed in several surgical applications wherein a device for engaging two portions of bone is required. Thus, while the screw is particularly adapted for insertion along medullary canals of the long bones, but may also be used in a similar manner in bone other than just along the medullary canal.

I claim:

1. A compression bone screw comprising:
   (a) a distal portion including a distal shaft having a plurality of distal threads therein, the distal threads having a given pitch, said distal portion terminating in a substantially pointed end;
   (b) a proximal portion including a proximal shaft having a diameter which is greater than the diameter of the distal shaft said proximal portion including a tool interengaging means thereon; and
   (c) an intermediate portion connecting the proximal portion and the distal portion, the intermediate portion including a tapered shaft having a threadless substantially annular smooth outer surface, wherein the tapered shaft and the distal threads cooperate so as to create opposing forces which effect compression of bone tissue between the intermediate portion and the distal portion when the distal threads and the tapered shaft are both engaging bone tissue.

2. The bone screw of claim 1 wherein the proximal shaft is cylindrical, the distal shaft is tapered and the cross-sectional diameter of the proximal shaft is greater than the largest cross-sectional diameter of the distal shaft.

3. The bone screw of claim 2 wherein the cross-sectional diameter of the proximal shaft is no smaller than the largest cross-sectional diameter of the distal threads.

4. The bone screw of claim 2 wherein the distal threads are provided with at least one self-cutting flute.

5. The bone screw of claim 4 wherein the distal portion terminates in a sharp trocar point.

6. The bone screw of claim 2 wherein the distal threads may be inserted into a bore formed longitudinally along the center axis of the fractured end of a bone and, by inserting the screw into the bore until the distal threads engage the bone on one side of the fracture and at least a part of the intermediate portion is engaging the bone on the opposite side of the fracture, a compressive force is established in the bone parallel to the length of the screw, said distal portion terminating in a sharp trocar point.

7. The bone screw of claim 1 wherein the proximal shaft has a plurality of proximal threads thereon, said proximal threads having a given pitch which is the same as the given pitch of the distal threads.

8. The bone screw of claim 7 wherein the proximal threads are provided with at least one self-cutting flute.

9. The bone screw of claim 1 wherein the proximal portion is provided with a recessed socket for engaging a tool.

10. The bone screw of claim 9 wherein said recessed socket is a recessed hexagonal opening.

11. A compression bone screw comprising:
   (a) a distal portion including a distal shaft having a plurality of distal threads thereon, the distal threads being provided with at least one self-cutting flute, the distal threads having a given pitch, and the distal portion terminating in a sharp trocar point;
   (b) a proximal portion including a cylindrical proximal shaft having a plurality of proximal threads

thereon, the proximal threads having the same given pitch as the distal threads, the proximal shaft having a diameter which is greater than the largest cross-sectional diameter of the distal threads; and the proximal portion being provided with a recessed socket adapted to be engaged by a tool for rotating said screw; and

(c) an intermediate portion connecting the proximal portion and the distal portion, the intermediate portion including a tapered shaft having a threadless substantially annular smooth outer surface, wherein the distal threads may be inserted into a bore formed longitudinally along the center axis of a fractured bone and, by inserting the screw into the bore until the distal threads engage the bone on one side of the fracture and at least a part of the intermediate portion is engaging the bone on the opposite side of the fracture, the tapered shaft and the distal threads cooperate so as to create opposing forces which effect compression of bone tissue between the intermediate portion and the distal portion, the compressive force thus established being parallel to the length of the bone and the length of the screw, with the screw further establishing axial alignment of the bone at the fracture site.

12. The bone screw of claim 11, wherein said intermediate portion is of approximately the same length as said distal portion and said proximal portion.

13. A compression bone screw comprising:

(a) a distal portion including a distal shaft having a plurality of distal threads thereon, the distal threads having a given pitch;

(b) a proximal portion including a proximal shaft having a plurality of proximal threads thereon, the proximal shaft having a diameter which is greater than the diameter of the distal shaft, said proximal threads terminating about midway along said proximal shaft and

(c) an intermediate portion connecting the proximal portion and the distal portion, the intermediate portion including a tapered shaft having a substantially smooth outer surface, wherein the tapered shaft and the distal threads cooperate so as to create opposing forces which effect compression of bone tissue between the intermediate portion and the distal portion when the distal threads and the tapered shaft are both engaging bone tissue, said intermediate portion being of a approximately the same length as said distal portion and said proximal portion.

* * * * *

United States Patent [19]

Perren et al.

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[45] **Date of Patent: May 28, 1991**

[54] **BONE SCREW**

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[21] Appl. No.: **437,581**

[22] Filed: **Nov. 17, 1989**

[30] **Foreign Application Priority Data**

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[51] **Int. Cl.**[5] **A61B 17/58**

[52] **U.S. Cl.** **606/61;** 606/73

[58] **Field of Search** 606/60, 61, 72, 73

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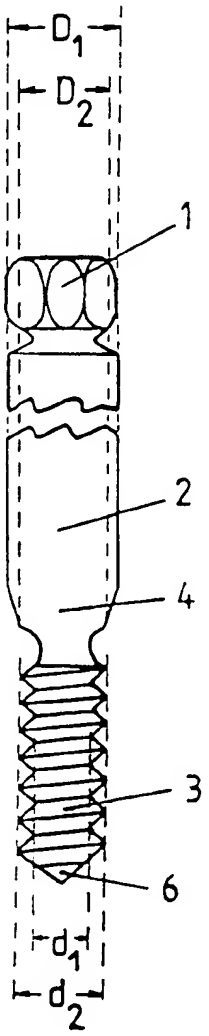
Attorney, Agent, or Firm—Davis Hoxie Faithfull & Hapgood

[57] ABSTRACT

A bone screw has a smooth shaft segment, a threaded segment and a tapered transition segment between the shaft and the threaded segment.

13 Claims, 1 Drawing Sheet



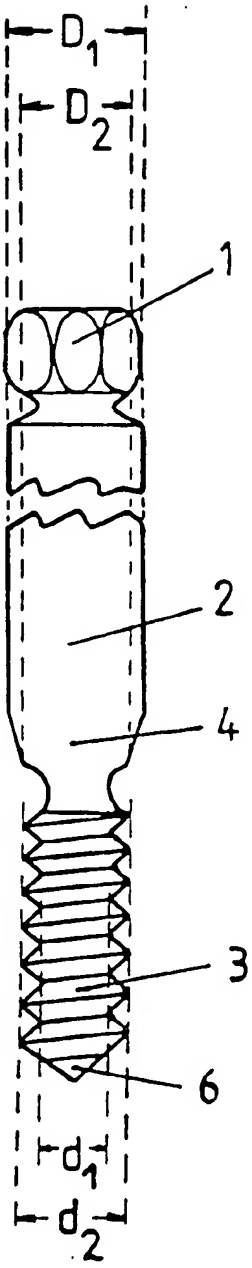


Fig. 1

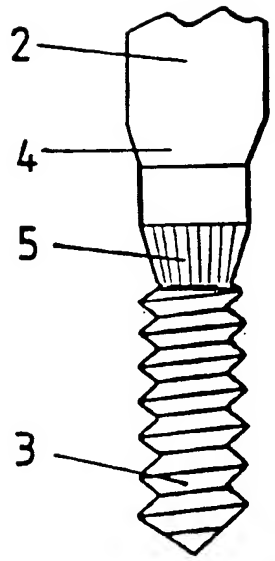


Fig. 2

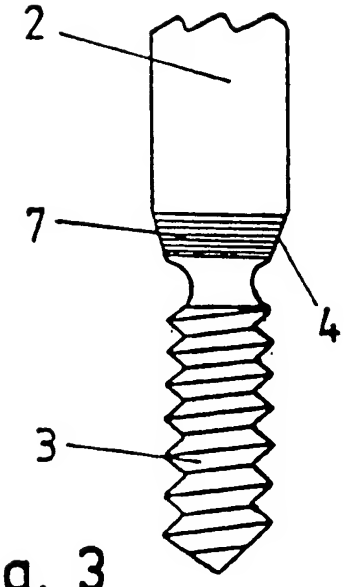


Fig. 3

BONE SCREW

FIELD OF THE INVENTION

This invention relates to bone screws and particularly to bone screws of the so-called Schanz type. Such screws have a screw head, a smooth shank segment, and a threaded segment.

BACKGROUND OF THE INVENTION

With conventional designs of Schanz screws, with any additional load on the screw in a radial direction, the driving pressure is reinforced on one side while being relieved on the other because of the absence of pre-stress. This can lead to a loosening of the screw and subsequent bone resorption. (cf. S. M. Perren, R. Ganz, and A. Ruter, *Med. Orthop. Technik*, Heft 1/75, 95 Jahrg. (1975) pp.6–10). In addition, with conventional Schanz screws, two drilling procedures are necessary, one with a drill for the minor diameter d_1 and the other with a drill for the major diameter d_2. If one tries to simplify the procedure by forming a single, undersized hole, micro and macro fractures occur in the bone material.

In conventional Schanz screws the transition between the shank and thread segments, both of which have the same outside diameter, is formed as a channel that either punches the bone material along its leading edge or cuts it along its back edge. There is not merely a radial spreading of the bone material.

SUMMARY OF THE INVENTION

In accordance with the invention, a bone screw is provided which can be inserted with only one drilling procedure, under radial compression of the bone material, without bone injury, and which retains the radial driving pressure along with the entire surface even under additional functional loads.

Such results are obtained in accordance with the invention by means of a bone screw having a head, a smooth shaft segment having a diameter D_1, adjacent said head, a threaded segment, and a transition segment between the shaft segment and the threaded segment, said transition segment tapering from a diameter D_1 adjacent the shaft segment to a diameter D_2 adjacent the threaded segment, the ratio

$$\frac{D_1 - D_2}{D_2}$$

being less than the breaking elongation of the bone.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be further described with reference to the accompanying drawings in which:

FIG. 1 is a view in elevation, partly broken away, of a bone screw in accordance with the invention.

FIG. 2 is a view in elevation of a fragment of a modified version of the bone screw of FIG. 1.

FIG. 3 is a view in elevation of a fragment of a differently modified version of the bone screw of FIG. 1.

DETAILED DESCRIPTION OF THE INVENTION

Referring to FIG. 1, a bone screw according to the invention comprises a screw head 1, a smooth shaft segment 2, having a diameter D_1 and a threaded segment 3 having a minor diameter d_1 and a major diameter d_2. Between the shaft segment 2 and the threaded segment 3 is located a tapered transition segment 4. In the embodiment shown in FIG. 1 the transition segment is conically shaped and narrows continuously from diameter D_1 to a lesser diameter D_2. The free end 6 of the threaded segment 3 is constructed as an automatically expanding screw tip (Trocar tip).

The breaking elongation of a bone will normally be about 2-3%. The size of the transition segment should be selected so that the ratio

$$\frac{D_1 - D_2}{D_2}$$

is less than the breaking elongation of the bone, say from about 0.001 to about 0.040 preferably between about 0.010 and 0.030. This range will result in optimum compression of bone material.

The diameter D_2 at the narrower end of the transition segment should advantageously correspond to the major diameter d_2 of the threaded segment to guarantee sufficient compression of the bone material by the smooth shaft segment.

The threaded segment is preferably dimensioned so that the ratio between the minor and major diameter, d_1/d_2 is between about 0.80 and about 0.89, preferable between about 0.83 and about 0.86.

To prevent simultaneous action by the threaded segment on the rear corticalis and by the transition segment on the front corticalis, which would lead to loss of control when the bone screw is screwed in, it is advantageous to position the transition segment at a distance of from about 11 to about 15 mm, preferably from about 12 to about 14 mm from the free end of the threaded segment, i.e., the end remote from the transition segment.

In a specific example of a screw according to FIG. 1 the shaft segment may have a diameter D_1 of 4.5 mm, and the threaded segment may have major and minor diameters of 4.4 mm and 3.8 mm, respectively. The end of the transition segment has a diameter, D_2, equal to 4.4 mm, the major diameter d_2 of the thread. The distance between the transition segment 4 and the tip of segment 3 is about 13 mm.

In FIG. 2 there is shown a modification of a screw according to the invention in which a milling segment 5 having straight longitudinal lands and groves is interposed between the transition segment 4, which is constructed as a shoulder, and the threaded segment 3.

A further embodiment of the invention is shown in FIG. 3. There the transition segment 4 is formed with a shallow thread. This will ensure further advance of the screw into the bone, even before the rear cortical wall is reached.

What is claimed is:

1. A bone screw having a head, a smooth shaft segment having a diameter D_1 adjacent said head, a threaded segment and a transition segment between the smooth shaft segment and the threaded segment, said transition segment tapering from a diameter D_1 adjacent said smooth shaft segment to a lesser diameter D_2 adjacent said threaded segment, the ratio

$$\frac{D_1 - D_2}{D_2}$$

being between 0.001 and 0.040.

2. The bone screw claimed in claim 1, wherein the ratio is between 0.010 and 0.030.

3. The bone screw claimed in claim 1, wherein the transition segment has a self-cutting thread.

4. The bone screw claimed in claim 1, wherein the transition segment narrows continuously from D_1 to D_2.

5. The bone screw claimed in claim 1, wherein the transition segment has a shallow thread.

6. The bone screw claimed in claim 1 and comprising a milling segment between the threaded segment and the transition segment.

7. The bone screw claimed in claim 1, wherein the threaded segment has a minor diameter d_1 and a major diameter d_2, the ratio d_1/d_2 being between about 0.80 and 0.89.

8. The bone screw claimed in claim 7, wherein the ratio is between about 0.83 and 0.86.

9. The bone screw claimed in claim 1, wherein the threaded segment has an automatically expanding screw tip at its end remote from the transition segment.

10. The bone screw claimed in claim 9, wherein the tip is a Trocar tip.

11. The bone screw claimed in claim 1, wherein the transition segment is from about 11 to about 15 mm from the remote end of the threaded segment.

12. The bone screw claimed in claim 11, wherein the transition segment is from about 12 to about 14 mm from the remote end of the threaded segment.

13. The bone screw claimed in claim 1, wherein the tip of the threaded segment has a corkscrew shape.

* * * * *

United States Patent [19]

Ross

[11] **Patent Number: 5,019,079**

[45] **Date of Patent: May 28, 1991**

[54] **BONE SCREW**

[75] Inventor: **Randall D. Ross**, Largo, Fla.

[73] Assignee: **Zimmer, Inc.**, Warsaw, Ind.

[21] Appl. No.: **438,879**

[22] Filed: **Nov. 20, 1989**

[51] **Int. Cl.**[5] **A61F 5/04**; F16B 35/00

[52] **U.S. Cl.** 606/72; 606/73; 411/389

[58] **Field of Search** 606/65, 72, 73, 66, 606/67, 68, 59; 411/383, 384, 389, 395

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Primary Examiner—Robert A. Hafer
Assistant Examiner—Michael Brown
Attorney, Agent, or Firm—Epstein, Edell & Retzer

[57] ABSTRACT

A guided bone screw includes proximal and distal sections threaded with different pitches in the same direction and spaced by an unthreaded intermediate section having a shorter length than the distal section with a diameter substantially equal to the major diameter of the distal section. The intermediate section diameter is greater than the minor diameter and smaller than the major diameter of the proximal section thread. The threads of both the distal and proximal sections are self-tapping. A guide bore for a guide wire extends the entire length of the screw. Two drive recesses are disposed in the proximal screw end on opposite sides of the guide bore for engagement by a two-pin screwdriver. The unthreaded intermediate section radially fills the bone bore in which it is implanted to provide lateral stability for the bone screw.

18 Claims, 1 Drawing Sheet

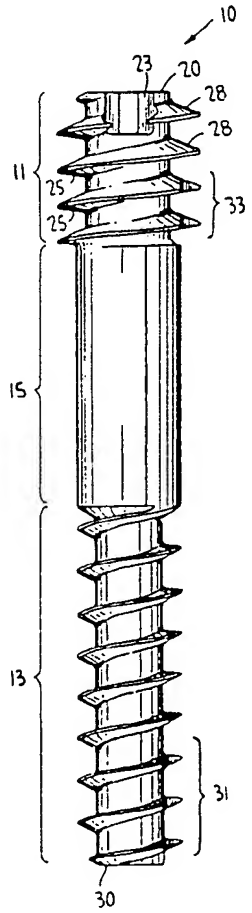


FIG. 1

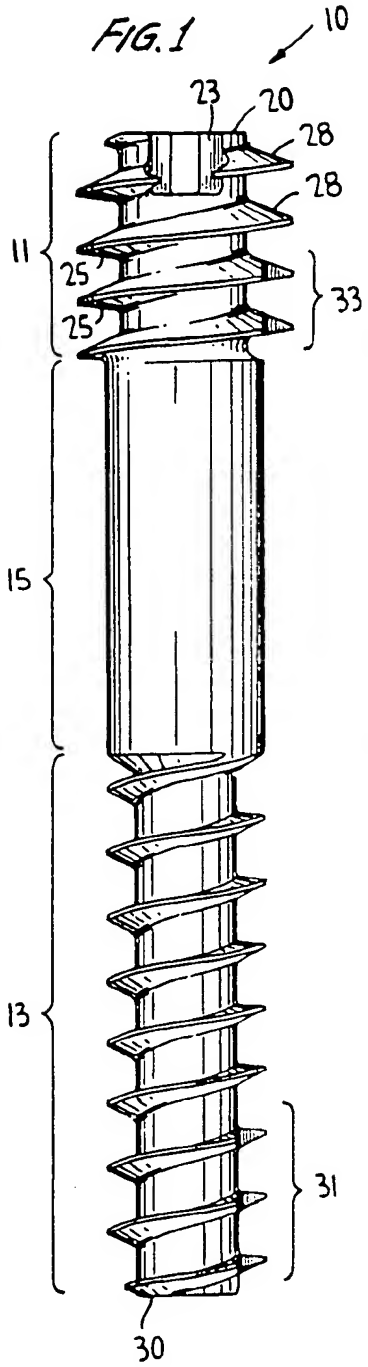


FIG. 3

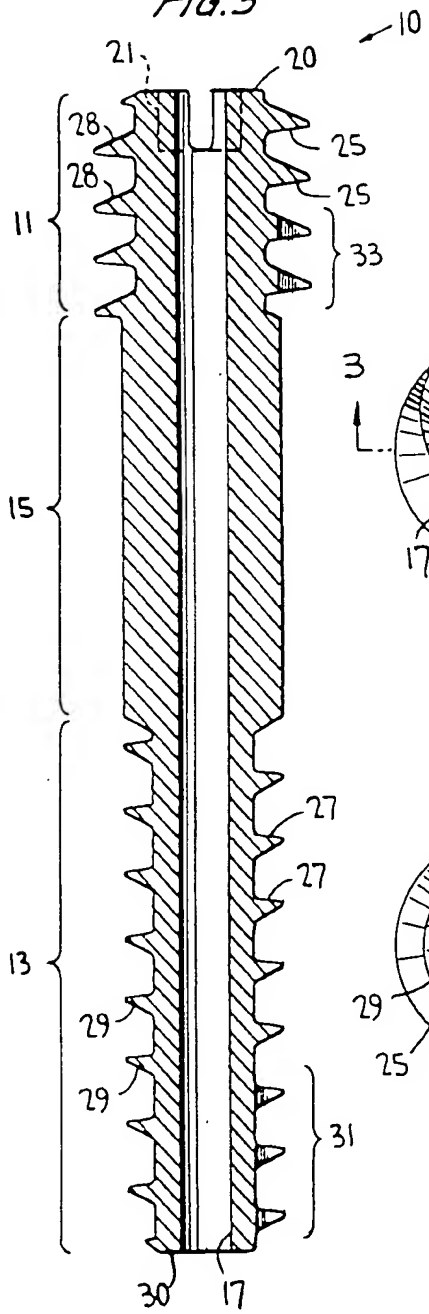


FIG. 2

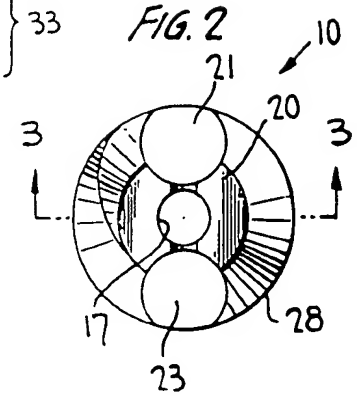
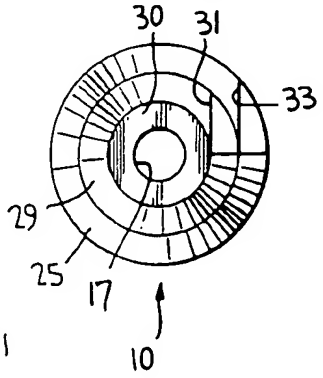


FIG. 4



BONE SCREW

BACKGROUND OF THE INVENTION

1. Technical Field:

The present invention relates to bone screws and, more particularly, to improvements in guided bone screws whereby safe insertion is facilitated and stability is enhanced.

2. Discussion of the Prior Art:

A prior art bone screw disclosed in U.S. Pat. No. 4,175,555 (Herbert) has like-handed thread at its distal and proximal ends separated by an unthreaded intermediate section. To function as a compression screw the proximal end thread pitch is less than the distal end thread pitch. Thus, when the screw is advanced in pretapped bores through two severed bone fragments being joined, the large pitch distal end of the screw advances a greater distance in the remote bone fragment, per screw turn, than the distance advanced by the proximal end of the screw in the near bone fragment. The result is a compression of the bone fragments at the fragment interface.

The Herbert bone screw described above has certain drawbacks that affect its practical utilization. For example, the diameter of the unthreaded intermediate section is smaller than the major diameter of the threaded distal end, and smaller than the minor diameter of the threaded proximal end. As a consequence, the unthreaded intermediate section resides in a bore section that must be large enough to accommodate the minor diameter of the proximal end thread and, therefore, does not fill the bore. The result is a lateral instability that sacrifices the integrity of the fragment interface during the healing process.

The unthreaded intermediate section of the Herbert bone screw is also required to be axially longer than each of the threaded end segments. The stated reason for this requirement is to assure that there is no thread at the fragment interface. While it is necessary to avoid thread at the fragment interface, the elongation of the intermediate screw section in the Herbert screw results in axially short threaded sections (i.e., fewer turns) and, consequently, less available compressive forces at the interface.

In addition, the unthreaded intermediate section of the Herbert bone screw is required to have a diameter that is smaller than both the major and minor diameters of the proximal end thread. This adds to the lateral instability described above. More specifically, the pretapped bore in the proximal bore section must be diametrically wider than the smaller diameter intermediate section. As a result, the portion of the intermediate section residing in that bore does not fill the bore.

OBJECTS AND SUMMARY OF THE INVENTION

It is therefore an object of the present invention to provide a bone screw in which the disadvantageous features noted above are avoided.

It is another object of the present to provide a bone screw configured to remain laterally stable when implanted.

A further object of the present invention is to provide a bone screw that is capable of exerting increased compression forces, as compared to prior art bone screws, without increasing the length or width of the screw.

In accordance with the present invention a bone screw has self-tapping proximal and distal threaded sections separated by an intermediate unthreaded section. The distal threaded section is longer than the intermediate section to provide additional gripping threads on the screw. The diameter of the intermediate section is substantially the same as the major diameter of the distal threaded section to permit the intermediate section to fill the section of the bone bore overlapping both the near and remote bone fragments for improved lateral stability. The intermediate section diameter is also larger than the minor diameter of the proximal threaded section to permit the intermediate section to fill the bore section residing only in the proximal or near bone fragment for additional lateral stability. The self-tapping threads at the proximal and distal sections eliminate the need for a separate bore-tapping step by the surgeon as part of the screw implantation procedure.

The bone screw is cannulated for use with a guide wire in a well-known manner. Two recessed drive bores at the proximal end of the screw are adapted to receive a two-pin drive device for easily controlled insertion of the screw. The thread on both the distal and proximal ends is provided with a substantially flat radial surface facing the bone fragment interface to maximize the thread surface area through which the compressive forces are applied to the bone fragments.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other objects, features and many of the attendant advantages of the present invention will be appreciated more readily as they become better understood from a reading of the following description considered in connection with the accompanying drawings wherein like parts in each of the several figures are identified by the same reference characters, and wherein:

FIG. 1 is side view in elevation of a bone screw constructed in accordance with the present invention;

FIG. 2 is a top view in plan of the bone screw of FIG. 1;

FIG. 3 is a view in longitudinal section taking along lines 3—3 of FIG. 2; and

FIG. 4 is a bottom view in plan of the bone screw of FIG. 1.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to the drawings in greater detail, a bone screw 10 of the present invention includes a threaded longitudinal section 11 terminating at proximal end 20, a threaded longitudinal section 13 terminating at distal end 30, and an unthreaded cylindrical intermediate section or shank 15 extending between the two threaded sections 11 and 13. A guide bore 17 is defined entirely through screw 10 along its central longitudinal axis between proximal end 20 and distal end 30. The proximal end 20 has two generally cylindrical and similarly configured recesses 21, 23 defined therein so as to extend a short longitudinal distance on diametrically opposite sides of guide bore 17. Recesses 21, 23 serve to receive cylindrical pins of a drive tool (not shown) that may be rotated to drive the screw into a bore defined through two bone fragments at a fracture site. The diameter of recesses 21, 23 in the illustrated embodiment is sufficiently large that the recesses extend radially beyond the flat end surface 20 and into the initial threads of proximal threaded section 11.

The threads of sections 11 and 13 are like-handed; that is, they extend in the same angular direction about the screw. The pitch of the threaded distal end section 13 is slightly greater than the pitch of the threaded proximal end section 11. Accordingly, when the screw is rotatably driven into a bone bore, the distal end section 13 tends to advance a small amount further than the proximal end section 11 with each rotation of the screw. This creates tensional forces in the screw which, in turn, applies compression forces to the bone fragments in the direction toward the fragment interface. To more efficiently apply these forces, the threads of the two sections 11 and 13 are asymmetrical about their crests with each thread having a respective surface 25, 27 extending substantially radially (i.e., normal to the longitudinal axis of the screw when viewed in any plane containing that axis) so as to face intermediate section 15. The radial surfaces 25, 27 efficiently and uniformly distribute the compressive forces to the surrounding bone tissue in a direction parallel to the longitudinal dimension of the screw. The opposite respective surfaces 28, 29 of the thread are relatively acute to the screw axis and face in opposite directions generally toward proximal end 20 and distal end 30, respectively, of the screw.

For reasons that are described in detail below, the various sections of screw 10 have important relative dimensions. First, the diameter of intermediate section 15 is substantially the same as the major diameter (i.e., the diameter of the crest) of the threads in distal threaded section 13. Second, the length of distal threaded section 13 is somewhat greater than the length of the shank or the intermediate section 15. Further, the diameter of intermediate section 15 is greater than the minor diameter (i.e., the diameter at the root) of the threads in proximal end section 11.

In addition to the relative dimensions described above, the bone screw of the present invention is characterized by self-tapping threads on both the distal section 13 and the proximal end section 11. The self-tapping feature eliminates the need for a separate tapping procedure as part of the screw implantation process. More specifically, the first few lengths of thread of distal section 13 are provided with a flute 31 configured to present a cutting edge that is radial to the screw. A similar flute 33 is provided in the first few lengths of thread in the proximal end section 11.

The bone screw of the present invention is typically employed to repair fractures of small bones, such as acute fractures of the volar (i.e., wrist) scaphoid bone. In order to employ bone screw 10, it is first necessary to drill bores through the bone fragments. A narrow bone bore, of diameter approximately equal to the minor diameter of distal threaded section 13, is drilled through the near bone fragment, past the fragment interface, and into the far bone fragment to a depth at least long enough to accommodate the entire length of threaded distal section 13. A wider bone bore, disposed concentrically with the narrow bore, is drilled through the near bone fragment and a short distance past the fragment interface into the far bone fragment. The wide bore has a diameter approximately equal to the diameter of the intermediate section 15. The two bores may be formed as a part of a single step using a stepped drill. A guide wire is inserted through the narrow and wide bone bores, either as part of the drilling process or afterward. Screw 10 is inserted onto the guide wire via guide bore 17 to properly position distal end 30 of the screw at the base of wide bone bore and the entrance to the narrow bone bore. Then, with the use of an appropriate two-pin driving tool engaging drive bores 21, 23, the bone screw is driven into the bone bores. The self-tapping feature provided by flutes 31, 33 in sections 13, 11, respectively, causes appropriate threads to be formed in the bone bores to engage the threaded screw sections. As defined above, the self-tapping features of both threaded sections 11 and 13 avoids the need for the surgeon to employ a self-tapping procedure after the bone bores are drilled.

Bone screw 10 is preferably inserted into the fracture site until the proximal end 20 is flush with or recessed below the exposed surface of the near bone fragment, thereby eliminating any protrusion of the screw from the bone that might otherwise interfere with normal use of the joint. When the screw is thusly inserted, intermediate section 15 extends between the two bone fragments across the fragment interface. The forward end of the intermediate section extends slightly into the distal or narrow bone bore as threaded by the self-tapping section 31 of the thread on distal section 13. The remainder of intermediate section 15 resides in the wider or proximal bone bore having substantially the same diameter as intermediate section 15. Accordingly, intermediate section 15 completely fills these bone bore portions and thereby precludes lateral movement of the screw, particularly at the bone fragment interface.

Threaded distal section 13 is axially longer than intermediate section 15, typically by fifteen to twenty-five percent. In the preferred embodiment of the invention, threaded distal section 13 is between seventeen and eighteen percent longer than intermediate section 15. Therefore, for a screw of given overall length, the bone screw 10 of the present invention provides more thread in distal section 13, and hence a greater surface area 27, than for a screw wherein the unthreaded intermediate section is required to be longer than the distal threaded section.

Although bone screw 10 can be fabricated from a variety of materials, the preferred material is titanium which has negligible susceptibility to corrosion and exhibits excellent biocompatibility.

In the preferred embodiment of bone screw 10, the facing thread surfaces 25, 27 that apply the compressive forces to the bone fragments are disposed at an angle 5° or less to normal or radial from the screw axis. The acute thread surfaces 28, 29 are typically at angles of 20° and 25°, respectively, to normal. The pitch of the thread along distal section 13 is 0.047 inch, and along proximal section 11 is 0.043 inch. The thread at proximal section 11 has a major diameter of 0.157 inch and the minor diameter of 0.094 inch; the thread at distal section 13 has a major diameter of 0.118 inch and a minor diameter of 0.075 inch. The diameter of intermediate section 15 is 0.118 inch. Bone screw 10 can be made in different lengths to compress different size fractures for different size bones. In one embodiment, wherein the bone screw is 0.630 inch in length, distal threaded section 13 is 0.245 inch long, intermediate section 15 is 0.208 inch long, and proximal threaded section 11 is 0.177 inch long. For another embodiment having a total bone screw length of 1.181 inch, distal thread section 13 is 0.542 inch long, intermediate section 15 is 0.462 inch long, and proximal thread section 11 is 0.177 inch long.

The dimensions set forth above are by way of example only for preferred embodiments of the present invention. It is to be understood that the important aspects of the present invention reside in the relative di-

mensions described herein. In particular, the diameter of intermediate section 15 is equal to the major diameter of the threads of distal section 13, greater than the minor diameter of the threads of proximal section 11, and less than the major diameter of the threads of proximal section 11. In addition, distal threaded section 13 is longer than intermediate section 15. Another important feature of the bone screw of the present invention is the self-tapping nature of threaded sections 11 and 13. Finally, a feature of the invention resides in the two-point drive arrangement wherein two recesses 21, 23 are disposed on opposite sides of guide bore 17 at proximal end 20 in position to be engaged and rotatably driven by a screw driver having a corresponding two-pin drive tip.

From the foregoing description, it will be appreciated that the present invention makes available a novel guided bone screw having improved lateral stability and greater thread surface for a given screw length.

Having described a preferred embodiment of a new and improved bone screw in accordance with the present invention, it is believed that other modifications, variations and changes will be suggested to those skilled in the art in view of the teachings set forth herein. It is therefore to be understood that all such variations, modifications and changes are believed to fall within the scope of the present invention as defined by the appended claims.

What is claimed is:

1. A bone screw connecting two pieces of bone comprising:
- a distal end;
- a proximal end;
- a generally cylindrical unthreaded intermediate section having a predetermined diameter;
- a threaded proximal section extending from said proximal end to said intermediate section and having a first uniformly-pitched thread;
- a threaded distal section extending from said distal end to said intermediate section and having a second uniformly-pitched thread that is threaded in the same direction as said first threads;
- wherein the pitch of said second thread is greater than the pitch of said first thread; and
- wherein said second thread has a major diameter substantially equal to said predetermined diameter.

2. The bone screw according claim 1 wherein said first thread is self-tapping at its end adjacent said intermediate section, and wherein second thread is self-tapping at said distal end.

3. The bone screw according to claim 1 wherein said first thread has a major diameter larger than said predetermined diameter and a minor diameter smaller than said predetermined diameter.

4. The bone screw according to claim 1 wherein said distal section is axially longer than said intermediate section.

5. The bone screw according to claim 1 further comprising a central longitudinal guide bore extending the entire length of said bone screw between said distal and proximal ends, and wherein said proximal end has two longitudinal recesses defined therein on diametrically opposite sides of said guide bore for receiving respective drive pins of a screwdriver.

6. The bone screw according to claim 1 wherein said first and second thread each have a compressive force-applying surface facing said intermediate section and an opposite surface, said compressive force-applying surface defining a first angle within approximately 5° of perpendicular to the length dimension of said screw, said opposite surface defining a significantly greater second angle with said length dimension.

7. The bone screw according to claim 1 wherein said first thread is self-tapping at its end adjacent said intermediate section, and wherein said second thread is self-tapping at said distal end; and
- wherein said distal section is axially longer than said intermediate section.

8. The bone screw according to claim 1 wherein said first thread has a major diameter larger than said predetermined diameter and a minor diameter smaller than said predetermined diameter; and
- wherein said second thread has a major diameter substantially equal to said predetermined diameter.

9. A bone screw for connecting two pieces of bone comprising;
- a distal end;
- a proximal end;
- a generally cylindrical unthreaded intermediate section having a predetermined diameter;
- a threaded proximal section extending from said proximal end to said intermediate section and having a first uniformly-pitched thread;
- a threaded distal section extending from said distal end to said intermediate section and having a second uniformly-pitched thread that is threaded in the same direction as said first thread;
- wherein the pitch of said second thread is greater than the pitch of said first thread; and
- wherein said threaded distal section is axially longer than said intermediate section.

10. The bone screw according to claim 9 wherein said first thread is self-tapping at its end adjacent said intermediate section, and wherein said second thread is self-tapping at said distal end.

11. The bone screw according to claim 9 wherein said first thread has a major diameter larger than said predetermined diameter and a minor diameter smaller than said predetermined diameter.

12. The bone screw according to claim 9 wherein said second thread has a major diameter substantially equal to said predetermined diameter.

13. The bone screw according to claim 9 wherein said second thread has a major diameter substantially equal to said predetermined diameter; and
- wherein said first thread is self-tapping at its end adjacent said intermediate section, and said second thread is self-tapping at said distal end.

14. The bone screw according to claim 9 further comprising a central longitudinal guide bore extending the entire length of said bone screw between said distal and proximal ends, and wherein said proximal end has two longitudinal recesses defined therein on diametrically opposite sides of said guide bore for receiving respective drive pin of a screwdriver.

15. A bone screw for connecting two pieces of bone comprising:
- a distal end;
- a proximal end;
- a generally cylindrical unthreaded intermediate section having a predetermined diameter;
- a threaded proximal section extending from said proximal end to said intermediate section and having a first uniformly-pitched thread;
- a threaded distal section extending from said distal end to said intermediate section and having a sec-

ond uniformly-pitched thread that is threaded in the same direction as said first thread;

wherein the pitch of said second thread is greater than the pitch of said first thread;

wherein said first thread is self-tapping at its end adjacent said intermediate section and said second thread is self-tapping at said distal end; and

wherein said first thread has a major diameter larger than said predetermined diameter and a minor diameter smaller than said predetermined diameter.

16. The bone screw according to claim 15 wherein said second thread has a major diameter substantially equal to predetermined diameter.

17. The bone screw according to claim 15 wherein said distal section is axially longer than said intermediate section.

18. The bone screw according to claim 15 wherein the major diameter of said first thread is the largest lateral dimension of said bone screw.

* * * * *

US005743912A

United States Patent [19]

Lahille et al.

[11] Patent Number: 5,743,912

[45] Date of Patent: Apr. 28, 1998

[54] **UPPER FEMORAL EPIPHYSIS OSTEOSYNTHESIS IMPLANT**

[75] Inventors: **Michel Lahille**, Vauhallan; **Philippe Cottin**, Saint Remy Les Chevreuse; **Christian Maresca**, Marseilles, all of France; **Toshio Yamaguchi**, Kobe, Japan

[73] Assignee: **Biomat**, Saclay, France

[21] Appl. No.: **696,519**

[22] Filed: **Aug. 14, 1996**

[30] **Foreign Application Priority Data**

Aug. 23, 1995 [FR] France 95 10076

[51] **Int. Cl.**[6] **A61B 17/76**

[52] **U.S. Cl.** **606/65**; 606/69; 606/73

[58] **Field of Search** 606/65, 66, 62, 606/63, 64, 67, 68, 72, 73, 69, 70, 71, 61, 60

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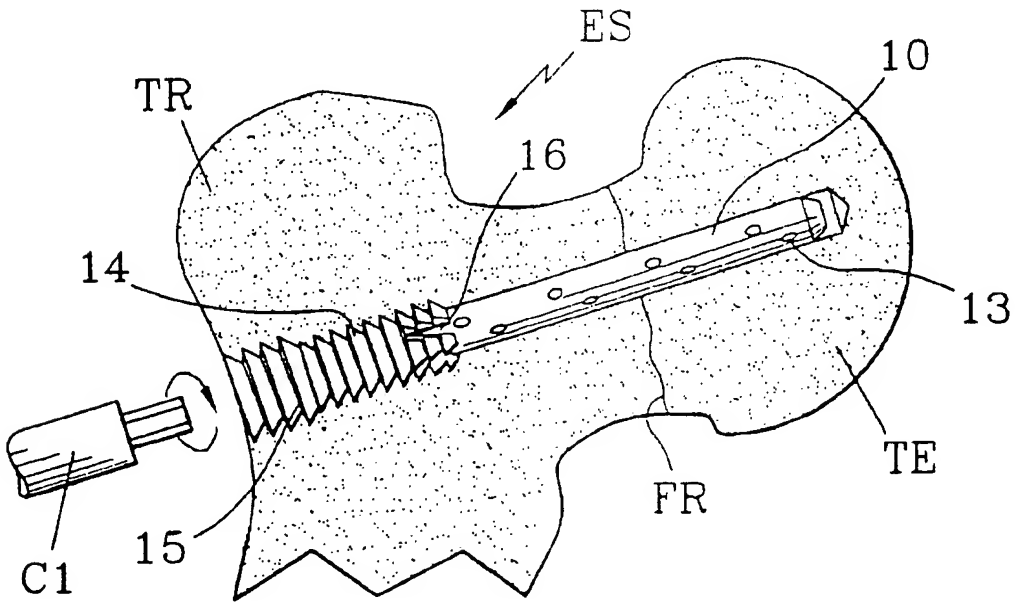
Primary Examiner—Guy V. Tucker

Attorney, Agent, or Firm—Laubscher & Laubscher

[57] **ABSTRACT**

A longitudinal revascularization conduit is formed in the body of an implant. It is blind at the distal end of the body to be implanted in one bone fragment, such as the trochanter, and open via transverse orifices and at the proximal end of the body to be implanted in another bone fragment, such as the femoral head. At least one self-tapping section situated at the distal end of the body immobilizes the body in the bone, or an anchor end-piece is slidably mounted on the body and contains a damping device adapted to push the end-piece in the proximal direction and the body in the distal direction in order to maintain the fracture in compression. The distal end of the body may be mounted in a cylindrical portion of a plate secured on the diaphysis of the femur.

12 Claims, 6 Drawing Sheets



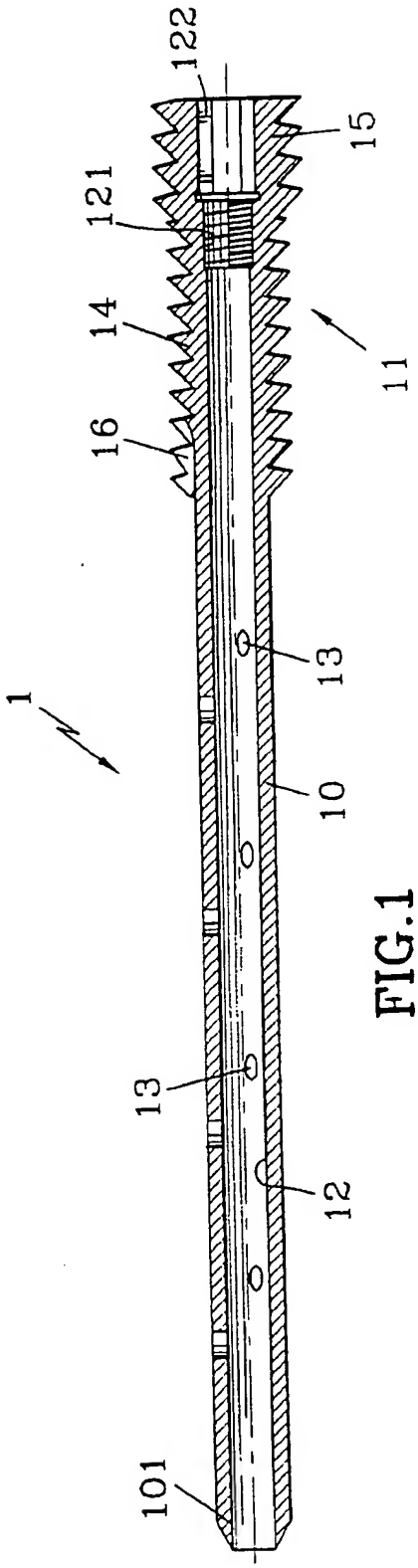


FIG.1

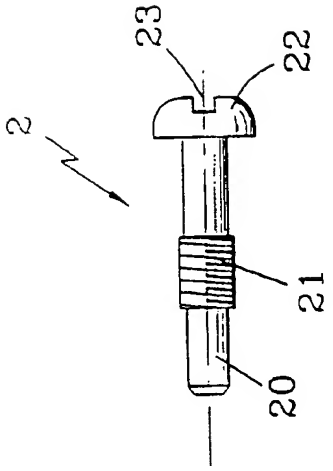


FIG.2

FIG.3

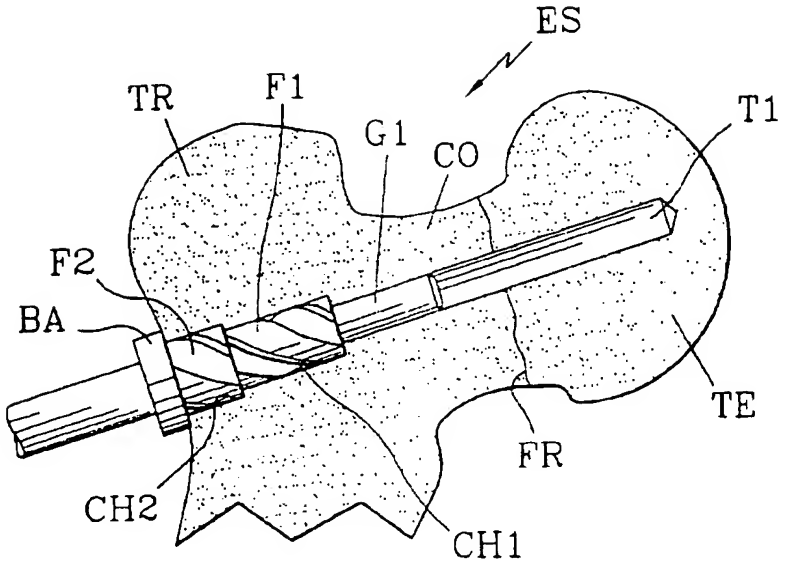


FIG.4

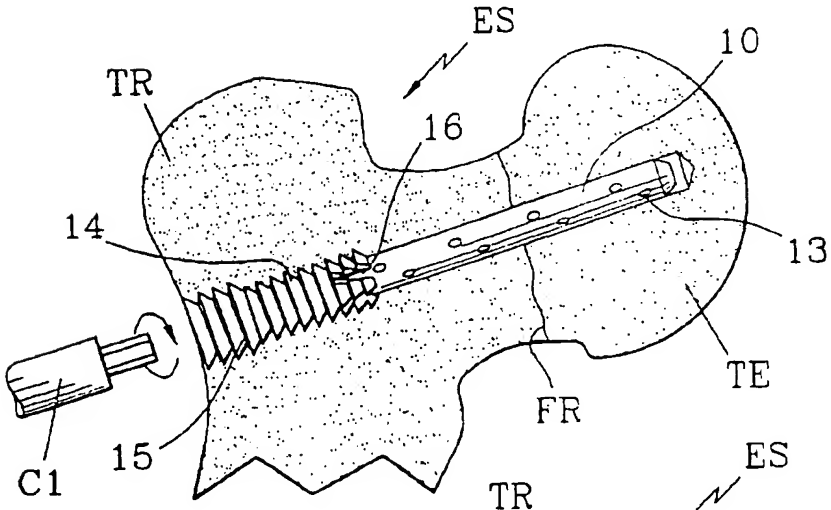
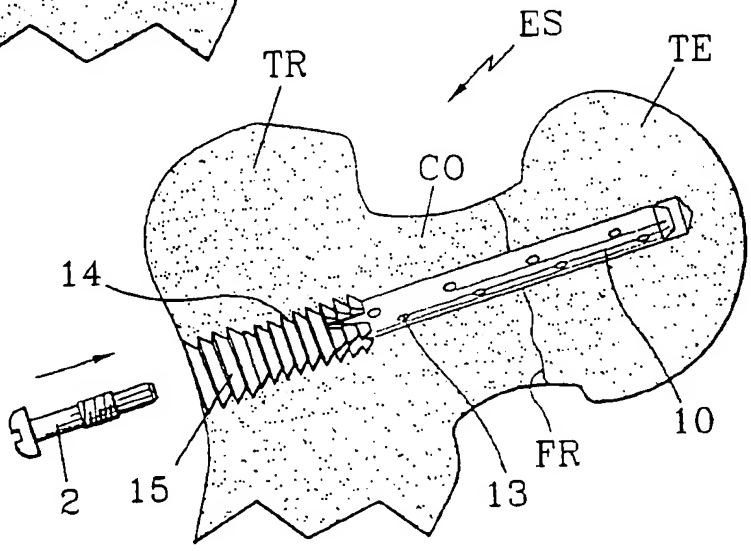


FIG.5



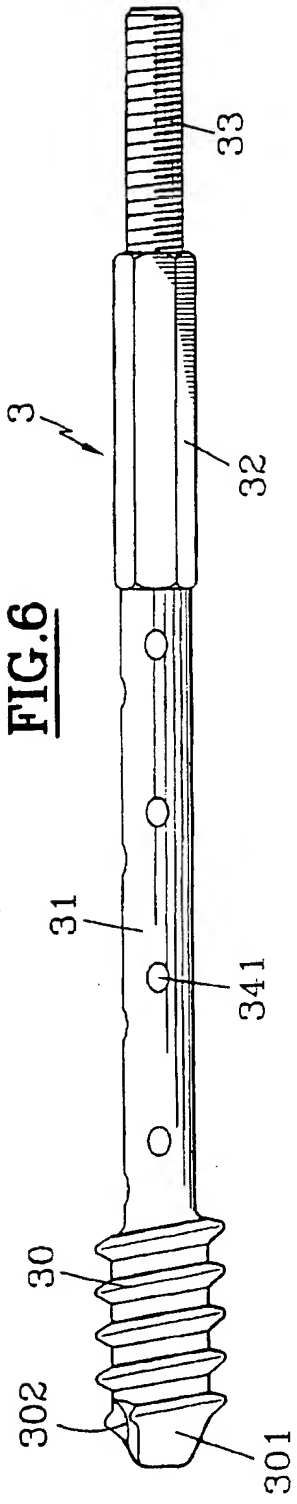

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FIG.6

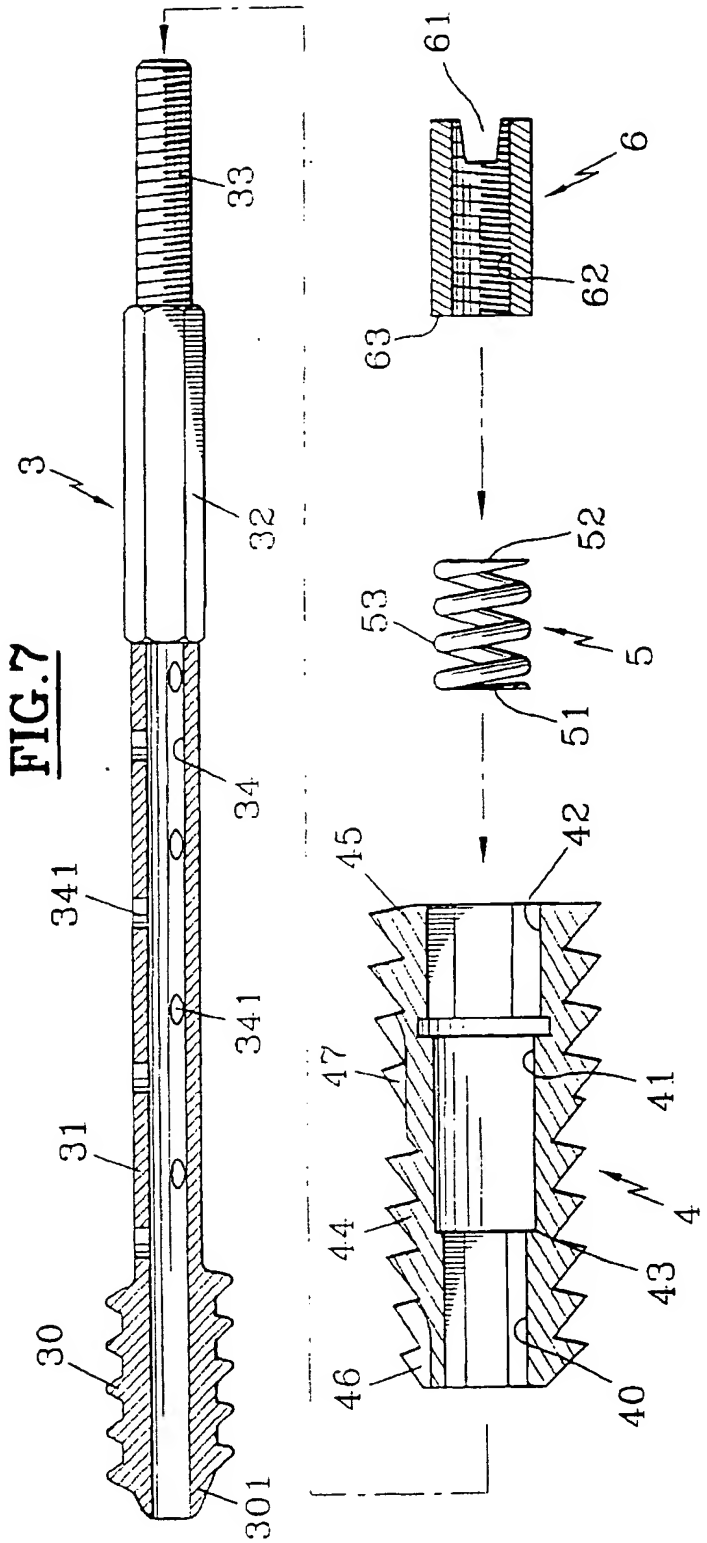
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FIG.7

FIG.8

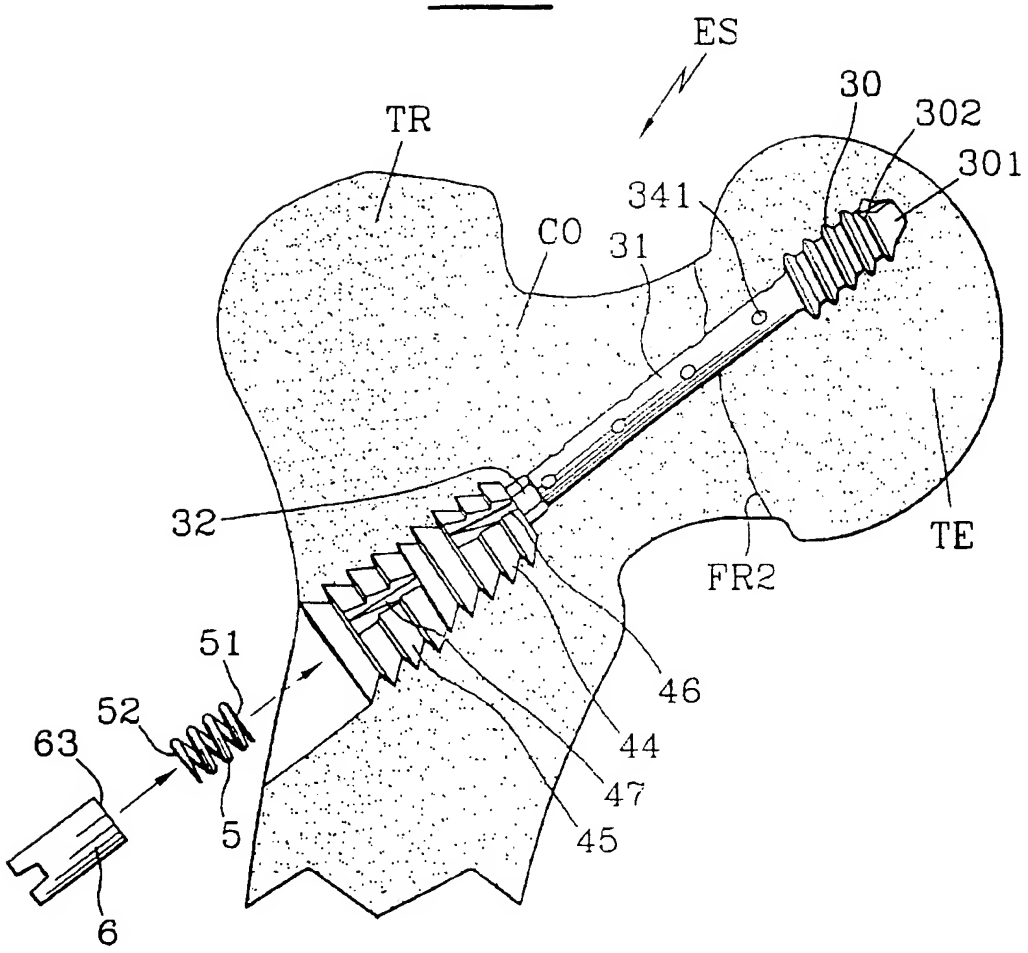
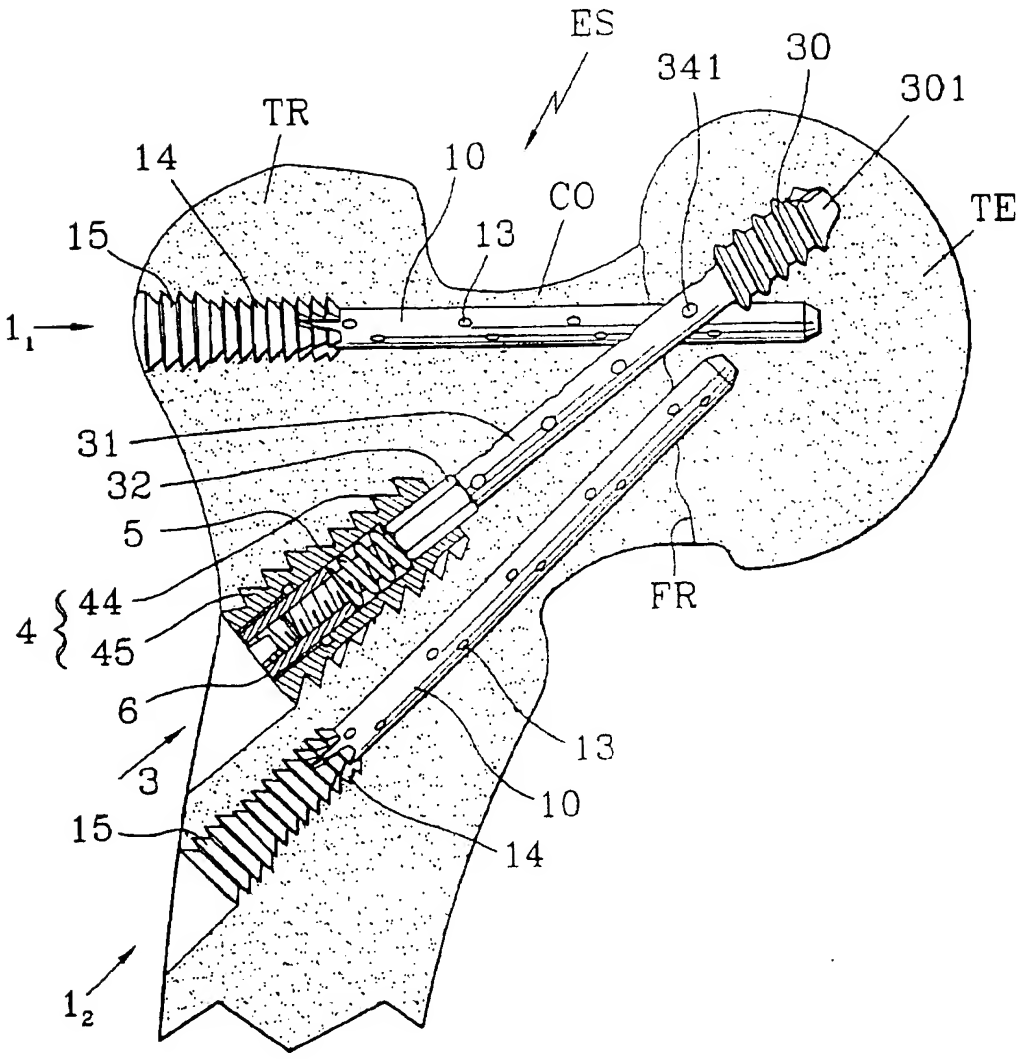


FIG.9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1_2

FIG.10

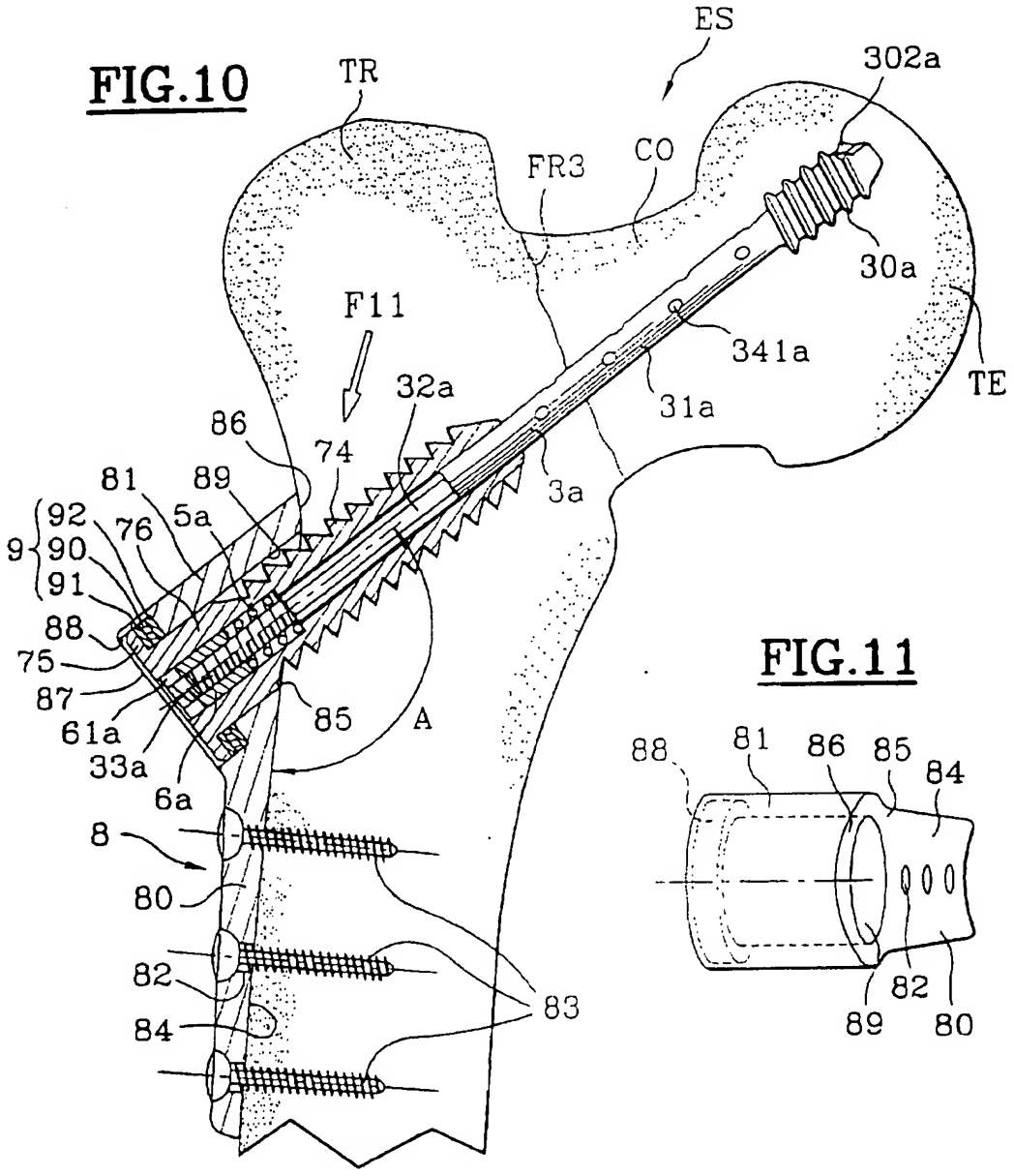
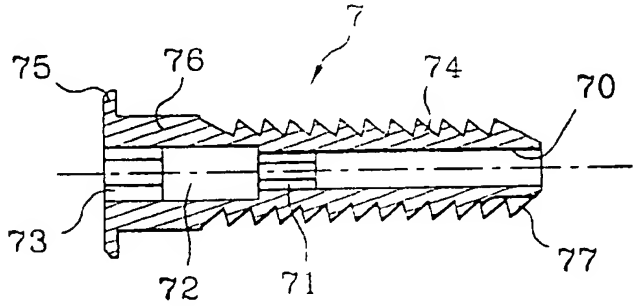


FIG.11

FIG.12



UPPER FEMORAL EPIPHYSIS OSTEOSYNTHESIS IMPLANT

BACKGROUND OF THE INVENTION

1—Field of the Invention

The present invention concerns an implant in particular for upper femoral epiphysis osteosynthesis to hold together bone fragments separated by a localized fracture in the neck of the femur or under the head of the femur.

2—Description of the Prior Art

An osteosynthesis implant of this kind is in the form of an osteosynthesis metal plate, also known as a nail-plate or screw-plate, having a short upper branch and a long lower branch separated by an elbow. The plate mates substantially with the vertical profile of the external face of the femur between the upper epiphysis and the femoral diaphysis so that it can be fixed to this face. One or two long parallel self-tapping screws pass through the trochanter and the neck of the fractured femur and are screwed into the head of the femur. The usually countersunk head of this screw is buried in a countersink in the short upper branch of the plate applied to the external face of the epiphysis. Between three and eight shorter screws are screwed perpendicularly into the femoral diaphysis to hold the long lower branch of the plate against the external face of the diaphysis.

The fixing of the long branch of the plate to the diaphysis holds immobile the short branch on which a long screw bears in order to unite the femoral head fragment against the trochanter fragment.

The long solid screws cause an imbalance in the intracephalic pressure in the bone fragments at the center of the site of the necrosis where vascular irrigation has been eliminated as a result of the fracture. Further, the length of the plate and the large number of screws require a large operation field and a long operation.

OBJECT OF THE INVENTION

The main object of this invention is to provide an implant of long screw type enabling revascularization of a fragmented bone focus.

SUMMARY OF THE INVENTION

An implant for osteosynthesis of a fracture between a first bone fragment and a second bone fragment comprises an elongate rectilinear body having a self-tapping portion at a proximal end of the body to be implanted in the first bone fragment or at a distal end of the body to be implanted in the second bone fragment. Transverse orifices are provided in the body through which there opens a longitudinal conduit having a blind distal end and an open proximal end.

Although the implant of the invention can be used to join at least two bone fragments on either side of a fracture located in particular at the level of the bony epiphysis, it is intended in particular for osteosynthesis of an upper femoral epiphysis which is the location of a fracture at the level of the femoral neck or under the femoral epiphysis head. In this latter case, the first bone fragment is part of the femoral head and the second bone fragment is part of the femoral trochanter.

According to a first embodiment, the longitudinal revascularization conduit is obstructed by a plug located at the distal end of the implant body. This plug is intended for preventing any extravasation from the longitudinal conduit to the external face of the epiphysis. The plug can be screwed in the distal end of the conduit; particularly, the distal end of the conduit comprises a screwthread into which a screwthreaded shank of the plug is screwed.

For screwing the body into a bored hole in the bone fragments, the distal end of the conduit comprises a counterbore opening to the exterior of the body and having a preferably polygonal cross-section to receive a complementary cross-section end of a key for screwing the body into the previously bored hole in the first and second bone fragments.

According to the first embodiment, the self-tapping portion is located at the distal end of the body whereby the body anchors in the second bone fragment, such as the trochanter. Preferably, the self-tapping portion comprises two screwthreaded sections having different screwthreads so as to immobilize in translation the body in the second bone fragment after bone forms around the body of the implant. The difference in the screwthreads between the two screwthreaded sections may be a difference between their pitches and/or may be a difference between their diameters.

According to an example of prefered embodiment, the self-tapping portion comprises a proximal screwthreaded section and a distal screwthreaded section having a pitch and/or a nominal diameter respectively greater than the pitch and/or the nominal diameter of the proximal screwthreaded section.

According to a second embodiment, the self-tapping portion is located at the proximal end of the body to be installed in the first bone fragment, such as femoral head. This self-tapping portion, as also in the first embodiment, can comprise at its distal end at least one longitudinal notch for starting screwthread cutting.

In the second embodiment, means are provided for compressing the fracture, i.e., for pressing the bone fragments together to obtain an assembly of maximal solidity without using any form of seating, such as an osteosynthesis plate, on the external face of the diaphysis. To achieve this compression, at the distal end of the body is provided an end-piece slidably mounted on an intermediate portion of the body and containing a damping means adapted to push the end-piece in the proximal direction and the body in the distal direction. In this way, the self-tapping portion anchored in the first bone fragment such as the femoral head is drawn towards the fracture and therefore towards the second bone fragment, such as the trochanter, and the end anchored in the second bone fragment is pushed in the opposite direction, also towards the fracture.

The damping means is preferably a coil spring which can be covered with a synthetic plastic material thereby slowing its expansion after implantation. The coil spring is housed in the end-piece so that a proximal end of the coil is pressed against an internal shoulder in the end-piece, and a member linked to the distal end of the body is placed against the distal end of the coil. This member can be a screwthreaded plug which is screwed onto a screwthreaded section at the distal end of the body and which is housed in a conduit internal to the end-piece.

More precisely, the end-piece can comprise an internal conduit including at least a proximal counterbore and an intermediate counterbore in the distal direction. The proximal counterbore can have a polygonal cross-section to slide on a polygonal cross-section intermediate portion of the body that can be substantially situated at the distal end of the longitudinal conduit in the body. The intermediate counterbore is preferably wider than the proximal counterbore to receive the damping means, such the above mentioned coil.

pressed against a shoulder between the proximal and intermediate counterbores. A member housed in the end-piece is linked to the distal end of the body to press the damping means against the shoulder.

To screw together the body and the end-piece respectively into the first and second bone fragments, in particular into the femoral head and the femoral trochanter, the internal conduit in the end-piece includes a distal counterbore, that may be wider than the intermediate counterbore, having a preferably polygonal cross-section to receive a complementary key for screwing the body and the end-piece respectively into the first and second bone fragments.

In an analogous manner to the self-tapping portion located at the distal end of the body in the first embodiment, the periphery of the end-piece according to the second embodiment may comprise a first self-tapping section. The pitch of the first self-tapping section is preferably substantially equal to that of the proximal self-tapping section of the body thereby facilitating the screwing both the end-piece and the proximal self-tapping portion of the body.

The periphery of the end-piece may comprise a second self-tapping section having a screwthread different from that of the first self-tapping section, if provided, and/or different from that of the self-tapping portion at the proximal end of the body, i.e., having a pitch and/or a diameter different from the respective ones of said self-tapping portion. This feature prevents any unscrewing of the end-piece and movement of the end-piece in the distal direction. According to an example, the periphery of the end-piece comprises at its proximal end the first self-tapping section and at its distal end the second self-tapping section that has a pitch and/or a nominal diameter respectively greater than the pitch and the nominal diameter of the first self-tapping section.

According to a third embodiment intended to consolidate sub-trochanter fractures, the implant further comprises a plate having an anchor portion adapted to be fixed against the diaphysis of the second bone fragment and a cylindrical portion through which the end-piece slides and against which a distal base of the end-piece is pressed. The cylindrical portion of the plate is oblique to the anchor portion of the plate whereby the body is held substantially perpendicular to the fracture.

The implant may comprise a means disposed between the distal base of the end-piece and the cylindrical portion of the plate for damping relative displacements between the end-piece and the plate.

The damping means comprises a damper material washer that is preferably in contact with one or two metal washers.

Preferably, a face of the plate to be applied to the diaphysis of the second bone fragment is transversely concave, and the cylindrical portion of the plate is truncated and has a base that is inclined to the axis of the cylindrical portion, transversely concave and longitudinally substantially convex. The plate mates thus the diaphysis face of the femur under the trochanter and distributes the progressive traction stress exerted on the end-piece and also hold axially the end-piece.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other objects, features and advantages of the invention will be apparent from the following detailed description of several embodiments of the invention with reference to the corresponding accompanying drawings, in which:

FIG. 1 is a longitudinal axial sectional view of a body of a first implant of the invention;

FIG. 2 is a longitudinal view of a plug of the body of the first implant;

FIG. 3 is a diagrammatic sectional view in a median-lateral plane of a femur upper epiphysis in which a hole and two counterbores have been bored for implanting the first implant;

FIG. 4 is a diagrammatic sectional view in a median-lateral plane of a femur upper epiphysis showing the screwing on of the first implant;

FIG. 5 is a view analogous to FIG. 4 showing the insertion of the plug into the first implant;

FIG. 6 is a longitudinal view of a body of a second implant of the invention;

FIG. 7 is an exploded view in longitudinal axial section of the second implant;

FIG. 8 is a diagrammatic sectional view in a median-lateral plane of a femur upper epiphysis showing the insertion of a spring and a plug into the body of the second implant already inserted into the epiphysis;

FIG. 9 is a diagrammatic sectional view in a median-lateral plane of a femur upper end in which two first implants and one second implant have been implanted;

FIG. 10 is a diagrammatic sectional view in a median-lateral plane of a femur upper epiphysis in which a third implant of the invention with a diaphysis plate is implanted;

FIG. 11 is a view of the diaphysis plate as seen in the direction of the arrow F11 in FIG. 10; and

FIG. 12 is a view in axial section of an end-piece of the third implant.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the following description of various embodiments of osteosynthesis implants in accordance with the invention, the dimensions of the various parts constituting the implants are given by way of non-limiting example. The bodies, plugs and end-pieces of the implants are made of metal, for example a titanium alloy.

In a first embodiment shown in FIGS. 1 and 2 an osteosynthesis implant comprises a cylindrical elongate rectilinear body 1 and a cylindrical plug 2.

The cylindrical elongate rectilinear body 1 comprises a proximal tubular vascularization portion 10 that is between 65 mm and 105 mm long, depending on the anatomy of the patient, and a distal anchor portion 11 that is 28 mm long. An internal conduit 12 having a diameter of 3 mm, except for two wider counterbores 121 and 122 at its distal end, extends along all of the length of the elongate rectilinear body 1.

The tubular portion 10 has an outside diameter of 5 mm at the time of machining the metal longitudinal rectilinear body and a final outside diameter of 5.4 mm to 5.5 mm following surface treatment. This treatment consists in depositing a first layer of T40 porous titanium 0.2 mm to 0.3 mm thick having a porosity lying between 20% and 40%. A layer of an osteogenic substance is then deposited on top of the first layer. This second layer is about 0.2 mm thick; it can be of a product that can comprise mother-of-pearl from mollusks or calcium carbonate $CaCO_3$ and lime, the calcium carbonate can be at least in part in the form of calcite and/or a smaller proportion of aragonite, and the lime can be quicklime CaO and/or hydrated lime $Ca(OH)_2$. The second layer covering the body 1 is preferably deposited by thermal sputtering, using a plasma torch, of a powder compound comprising one of the following constituents: aragonite,

calcite, quick lime and hydrated lime. This second layer facilitates reossification of the regeneration nucleus around the body of the implant.

The proximal end of the body terminates in a frustoconical portion **101**, or by a taper, analogous to that at the end of a hypodermic needle, to facilitate penetration of the body into a hole in the bone.

The tubular portion comprises a plurality of radial orifices **13** having a diameter of 1.8 mm leading into the longitudinal internal conduit **12**. These orifices are offset longitudinally and circumferentially along a helical path coaxial with the body and having a pitch of 18 mm. The radial orifices 13 are equally spaced along this helical path. In the embodiment illustrated in FIG. 1 there are three orifices **13** for each pitch of the helical path and they are equi-angularly distributed with an angular pitch of 120° and a longitudinal pitch 6 mm. The radial orifices **13** which communicate with each other through the longitudinal internal conduit **12** and the proximal end of the latter contribute to balancing the intracephalic pressure throughout the femoral head as far as the femoral trochanter after implantation of the body of the implant. The perforated tubular portion **10** constitutes a guide for revascularization by angionesis and, with the osteogenetic substance on the surface of the body, contributes to the growth of hard bone around the body 1 of the implant.

The distal anchor portion **11** is made up of two longitudinally juxtaposed sections having different exterior self-tapping screwthreads **14** and **15**.

The first screwthreaded section **14** is located at the distal end of the tubular vascularization portion **10** including the orifices **13**, in front of the second screwthreaded section 15. The first screwthreaded section has a nominal diameter of 8 mm, a coarse triangular pitch, known as an anti-recoil artillery pitch of 2 mm, and a screwthread root diameter of 6 mm.

The proximal end of the first screwthreaded section **14** includes three equi-angularly distributed notches **16** at 120° to each other, like the three radial orifices **13** in one pitch of the helical path previously mentioned in connection with the tubular portion **10**. The notches **16** have a bottom substantially flushing with the external surface of the tubular portion **10**. In a preferred embodiment, one of the walls of each notch is situated in a respective axial plane of the body **1** and the other wall of the notch is situated in the screwing direction of the screwthreads **14** and **15** at substantially 30° to 45° to the respective axial plane. The notches **16** are for starting screwthread cutting in the bone when the anchor portion **11** is inserted into a previously bored 6.5 mm diameter hole, this diameter being significantly greater than the screwthread root diameter of 6 mm, which facilitates the cutting of a screwthread in the hole by the screwthreaded section **14**.

The second screwthreaded section **15** has a nominal diameter of 9 mm, an anti-recoil artillery pitch of 2.2 mm and a depth of about 2 mm. The nominal diameter and the screwthread pitch of the second screwthreaded section 15 are therefore respectively greater than the nominal diameter and the pitch of the first screwthreaded section **14**. The difference in pitch between the first and second screwthreaded sections, which is equal to 0.2 mm, constitutes a means preventing an unscrewing of the body of the implant to prevent the body escaping from the epiphysis, after consolidation of the epiphysis bone around and in the threads of the anchor portion **11** of the body 1 screwed into the epiphysis bone.

As already mentioned, the distal end of the internal conduit comprises two counterbores **121** and **122**.

The first counterbore **121** situated substantially at the transition between the first and second screwthreaded sections **14** and **15** is screwthreaded with a nut inside diameter of 3.3 mm and a pitch of 0.7 mm. A screwthreaded intermediate section **21** of the plug **2** screws into the first counterbore.

The second counterbore **122** situated at the distal end of the body 1 and open towards the outside is in the form of a six-flats socket that circumscribes in cross-section at least the screwthreaded first counterbore **121**. The flats of the second counterbore 122 are 4 mm wide and 7 mm long. The second counterbore is adapted to receive the six-flats end of a special key, as shown in FIG. **4**.

Referring to FIG. 2, the plug **2** comprises a shank **20** having a length exceeding the sum of the lengths of the first and second counterbores **121** and **122** in the body **1**. The shank **20** is smooth with a distal diameter of 2.8 mm, significantly less than the diameter of the internal conduit **12** of the body 1, except for an intermediate screwthreaded section **21**. The intermediate screwthreaded section **21** is complementary to the first counterbore **121** so that it can be screwed into the latter. The distal end of the plug terminates in a flat head **22** with a diametral screwdriver slot **23**. In a different embodiment the head of the plug is a countersunk head which is received into a countersink provided at the distal end of the body 1 of the first implant, i.e. at the distal end of the counterbore **122**.

The plug 2 therefore hermetically closes off the distal end of the conduit **12** inside the body **1** of the first implant and therefore prevents any extravasation.

The first implant of the invention is implanted using the following four tools:

- a drill bit 2 mm in diameter and 200 mm long, i.e., having a length greater than the body 1 of the implant which varies between about 93 mm and about 133 mm, depending on the anatomy of the patient.
- a first hollow cutting tool having an inside diameter equal to 2.1 mm so that it is guided by the bit and an outside diameter of 5.5 mm in order to bore a hole having a diameter substantially equal to the outside diameter of the tubular portion **10** of the body **1** of the first implant; the hollow cutting tool is at least as long as the bit;
- a counterboring tool made up of:
  - a first guide G1 having an outside diameter of 5.2 mm and a length of 28 mm to enter the hole drilled by the first hollow cutting tool;
  - a first shape milling cutter F1 having an outside diameter of 6.5 mm and a length of 22 mm to bore a first counterbore to be self-tapped by the first screwthreaded section **14**; and
  - a second shape milling tool F2 having an outside diameter of 7.5 mm and a length of 10 mm to bore a second counterbore to be self-tapped by the second screwthreaded section **15**; and
- a first key C1 having one six-flats end complementary to the second counterbore **122** at the distal end of the body 1 of the first implant, i.e., having flats 4 mm wide and at least about 7 mm long.

FIGS. 3, 4 and 5 diagrammatically illustrate various steps of machining in the upper epiphysis ES of a femur in order to implant the first implant 1 of the invention. The upper epiphysis of the femur has a necrosis resulting from a fracture FR at the level of the femoral head TE.

The drill bit is first inserted into the upper epiphysis along an axis substantially perpendicular to the line of the fracture FR and extending from the base of the femoral trochanter

TR to the femoral head TE through the neck CO and therefore through the focus of the fracture. The insertion of the drill bit into the bone is in progress under the monitoring of a X-rays source. The blind hole formed in this way has a diameter of 2 mm and a depth significantly greater than the length of the first implant with the plug 2 screwed fully into the body 1.

The blind hole is widened into a 5.5 mm diameter hole T1 bored by means of the first cutting tool that fits around the first drill bit acting as a longitudinal guide. After this boring operation the first drill bit and the first cutting tool are withdrawn from the epiphysis ES.

The first and second counterbores are then milled in the trochanter TR, as shown in FIG. 3. The first milling guide G1 is threaded into the hole T1 that has just been bored in order to guide the two milling cutters. A stop ring BA with locking screw on the guide G1 limits the depth of the bores for the counterbores. The first shape milling cutter F1 widens the hole T1 in the first counterbore CH1 to a diameter of 6.5 mm, i.e., a diameter significantly greater than the screwthread root diameter of the first screwthreaded section 14 of the anchor portion 11. The length of the counterbore CH1 is substantially greater than the length of the section 14. The second shape milling cutter F2 then widens the counterbore CH1 to form the second counterbore of 7.5 mm diameter, i.e., a diameter significantly greater than the screwthread root diameter of the second screwthreaded section 15 of the anchor portion 11. The length of the second counterbore CH2 which opens onto the external face of the trochanter is substantially equal to the length of the second screwthreaded section 15 at the distal end of the implant body 1.

After removing the counterboring tool, the implant body 1 is placed in the femoral upper epiphysis ES, as shown in FIG. 4. The tubular portion 10 is driven into the long blind hole T1 using an impactor until the notched proximal end 16 of the first screwthreaded section 14 of the anchor portion 11 is flush with the external face of the trochanter. The six-flats end of the key C1 is inserted into the six-flats counterbore 122 of the implant body 1. Pressure is applied to the key C1 to engage the distal end of the first screwthreaded section 14 into the shoulder between the two counterbores CH1 and CH2 formed in the trochanter. The key C1 is then used as a screwdriver in order to screw the implant body 1 into the bone until the first and second screwthreaded sections 14 and 15 of the implant body 1 are entirely housed within the respective counterbores CH1 and CH2 made in the bone. As this screwing proceeds the screwthreaded sections 14 and 15 cut themselves a screwthread in the counterbores CH1 and CH2.

In this way the implant is finally implanted into the femoral upper epiphysis ES. Because of the difference in the pitches and because of the difference in the diameters of the screwthreaded sections 14 and 15, the body 1 cannot become unscrewed and move in the distal direction towards the external face of the epiphysis after bone forms around the body. The orifices 13 and the internal conduit 12 communicate on either side of the fracture FR, in the neck CO and the head TE, and bring about revascularization, i.e., irrigation between bone fragments eliminated by the fracture.

The key C1 is withdrawn. As shown in FIG. 5, the plug 2 is finally screwed into the screwthreaded counterbore 121 of the body 1 until the head 23 presses against the distal end face of the body and so blocks off the distal end of the internal conduit 12 of the implant body 1 which thereby becomes a blind bored conduit open only at the proximal end.

Referring now to FIGS. 6 and 7, a second osteosynthesis implant comprises an elongate rectilinear body 3 of generally cylindrical shape, like a stud bolt, a cylindrical distal end-piece with a double external screwthread 4, a helical spring 5 and a screwthreaded hollow plug 6.

The elongate rectilinear body 3 comprises from its proximal end towards its distal end, a proximal self-tapping screwthreaded tubular portion 30, a perforated smooth tubular portion 31, a hexagonal cross-section operating portion 32 and finally a screwthreaded distal portion 33.

A blind internal revascularization conduit 34 with a proximal mouth 3 mm in diameter is provided in the proximal portion 30 and the smooth portion 31. As in the first embodiment, plural radial orifices 341 1.8 mm in diameter are formed in the smooth tubular portion 31. These orifices are disposed along a helical path coaxial with the body 3 and regularly distributed in the longitudinal direction with an angular pitch of 120°. The orifices 341 communicate with each other via the longitudinal internal conduit 34 and with the mouth at the proximal end of the internal conduit, the latter being blind at the distal end at the level of the operating portion 32, as shown in FIG. 7.

As in the body of the first implant, the smooth tubular portion 31 has an outside diameter of 5.4 mm to 5.5 mm after thermal deposition on the surface of a porous titanium first layer and a second layer of a mother-of-pearl product or of a product including calcium carbonate in the form of calcite and/or aragonite and quick lime and/or hydrated lime. The smooth tubular portion 31 is made in different sizes between 20 mm and 60 mm in order to suit the anatomy of the patient.

The proximal portion 30 of the body 3 of the second implant designed to be implanted in the femoral head TE has an external screwthread over a length of 15 mm with a nominal diameter of 8 mm and a screwthread root diameter of 6 mm. This screwthread has a pitch of 3 mm with a particular self-tapping profile known as a spongy or soft bone screwthread profile. The self-tapping portion 30 has a proximal end 301 of frustoconical shape including two diametrally opposite notches 302 extending longitudinally as far as the start of the self-tapping screwthread. The notches 302 can be similar to the notches 16. The frustoconical end 301 with the notches 302 starts the cutting of a self-tapping screwthread in the bone.

The operating portion 32 and the screwthreaded portion 33 at the distal end of the body 3 are respectively 25 mm and 10 mm long.

As shown in FIG. 7, the distal end-piece 4 comprises an internal conduit made up of first, second and third sections having progressively larger cross-sections from the proximal end towards the distal end of the end-piece.

The first section 40 constitutes the proximal section of the internal conduit in the end-piece 4 and has a six-flats cross-section complementary to the hexagonal cross-section of the operating section 32 of the body 3. However, the 10 mm length of the end-piece section 40 is less than the 25 mm length of the hexagonal cross-section portion 32 of the body 3. The body portion 32 can therefore slide in the end-piece section 40 in the axial direction when the end-piece 4 is being fixed into the femoral trochanter TR to pull in the distal direction the body 3 anchored in the femoral head TE by the proximal self-tapping portion 30, as explained below. The polygonal cross-section sliding coupling between the portion 32 and the section 40 also enables screwing of the proximal self-tapping portion 30 of the body 3 together with screwthreaded portions on the periphery of the end-piece 4, as explained below.

The section 41 in the end-piece 4 is a smooth cylindrical section situated between the proximal and distal sections 40

and 42. It is 12 mm long. The 6.5 mm diameter of the smooth section 41 is greater than the greatest width of the hexagonal cross-section of the proximal section 40 but less than the greatest width of the hexagonal cross-section of the distal section 42 of the end-piece. The helical spring 5, the length of which when unstressed is 12 mm, and at least part of the plug 6, which have respective outside diameters of 6.3 mm and 6.4 mm, are completely housed within the intermediate end-piece section 41. The proximal end 51 of the spring 5 is pressed against an internal shoulder 43 between the sections 40 and 41 by the thrust exerted by the plug 6 pressed against the distal end 52 of the spring 5. The body portion 32 can pass through the spring 5 if necessary.

The turns of the spring 5 are covered with a synthetic plastic material, such as polyurethane, to form a sheath 53 around the turns which slows the expansion of the spring after it is compressed between the shoulder 43 and the plug 6. The synthetic plastic material sheath 53 around the turns of the spring also contributes to attenuation of micro-displacements and vibrations to which the second implant may be subjected after implantation.

The third section 42 of the end-piece 4 has a hexagonal cross-section and is located at its distal end. It has flats 4 mm wide and 8 mm long in order to receive the six-flats end of the previously mentioned key C1. When the proximal section 40 of the end-piece 4 is threaded over the operating portion 32 of the body 3, the distal screwthreaded portion 33 of the body passes freely through the other two sections 41 and 42 of the internal conduit in the end-piece 4. To push the spring 5 into its housing 41, the plug 6 is screwed onto the distal screwthreaded body portion 33 which has a nominal diameter of 4 mm and a fine pitch of 0.6 mm.

As also shown in FIG. 7, the periphery of the end-piece 4 has a first screwthreaded anchor section 44 at its proximal end and a second screwthreaded anchor section 45 at its distal end, in a similar way to the first and second screwthreaded sections 14 and 15 constituting the anchor portion 11 of the body 1 of the first implant.

The first screwthreaded section 44 has a nominal diameter of 11 mm, a screwthread root diameter of 9 mm and an anti-recoil artillery pitch of 3 mm identical to the pitch of the proximal body portion 30, and extends over a length of 20 mm, as far as the smooth cylindrical section 41 of the internal conduit. The proximal end of the first self-tapping section 44 includes three distributed notches 46 that are equally spaced in the axial direction with an angular spacing of 120° to start the cutting of a screwthread by means of the first section 44, in a similar manner to the notches 16 at the proximal end of the anchor portion 11 of the body 1 of the first implant.

The second screwthreaded section 45 has an outside diameter of 13 mm and an anti-recoil artillery pitch of 3.2 mm and extends over a length of 10 mm. The proximal end of the section 45 also includes three notches 47 equi-angularly distributed at 120° to start the cutting of a screwthread by means of the second section 45. The notches 47 can be offset in the radial direction relative to the notches 46, for example by about 60°.

The difference in pitch, 3.2−3=0.2 mm, between the two screwthreaded sections 44 and 45 prevents unscrewing of the end-piece 4.

The screwthreaded plug 6 has a length that is less than the sum of the lengths of the smooth intermediate section 41 and the hexagonal cross-section section 42 inside the end-piece, and that is less than the length of the distal screwthreaded portion 33 of the body 3 so that the plug 6 is guided in the smooth section 41 and can be moved a few millimeters in the axial direction inside the end-piece 4 by the compressed spring 5. The 6.4 mm outside diameter plug 6 has a slot 61 at its distal end by means of which its screwthreaded bore 62 is screwed onto the distal screwthreaded portion 33 of the body 3 so that its proximal face 63 pushes the spring 5 against the shoulder 43 of the proximal section 40 and the smooth intermediate section 41 inside the end-piece. The plug 6 therefore has two functions, to close the internal conduit in the end-piece at the distal end and to compress the damper spring 5.

The second implant is implanted using the following tools:

- the 2 mm diameter first drill bit, having a length greater than that of the body 3 of the second implant, which can vary between 70 mm and 110 mm depending on the anatomy of the patient;
- a second hollow cutting tool having an inside diameter equal to 2.1 mm so that it can be guided by the first drill bit and an outside diameter of 6 mm in order to bore a hole having a diameter substantially equal to the smallest screwthread root diameter of the threads on the second implant, which in this example is that of the proximal screwthreaded portion 30 of the body 3; the second hollow cutting tool is at least as long as the first drill bit;
- a second counterboring tool comprising:
  - a second guide having an outside diameter of 5.7 mm and a length of 28 mm to enter the hole bored by the second hollow cutting tool;
  - a third shape milling tool having an outside diameter of 9.5 mm and a length of 22 mm to bore a first counterbore to be self-tapped by the proximal end-piece section 44; and
  - a fourth shape milling tool having an outside diameter of 11 mm and a length of 10 mm to bore a second counterbore to be self-tapped by the distal end-piece section 45;
- the first special key C1 having a six-flats end complementary to the distal counterbore 42 of the end-piece, i.e., having flats 4 mm wide and a length of at least 8 mm;
- a second special key having a cylindrical end hole with a blind screwthread, which is similar to the plug 6, to be screwed onto the distal screwthreaded portion 33 of the body 3 and enters the internal end-piece sections 41 and 42 so as to pull the body 3, and especially the femoral head TE into which the proximal portion 30 is screwed, in the direction of the trochanter TR;
- tweezers for fitting the spring 5; and
- a screwdriver for screwing the plug 6 onto the screwthreaded body section 33 to compress the spring 5.

In reference to FIG. 8, the various stages of boring into the upper epiphysis ES of the femur to implant the second implant of the invention are shown. They are substantially the same as those shown in FIGS. 3 through 5. The second implant is more particularly suited to fractures FR2 of the neck of the femur sub-capital, trans-cervical or even basicervical, with varying Powles angle.

As with the first implant, the first drill bit is introduced into the upper epiphysis ES of the femur, through the trochanter TR, then the neck CO of the femur and finally part of the femoral head TE in order to form a blind hole substantially perpendicular to the fracture FR2. The depth and the direction of this hole are monitored by X-rays so that the length bored in this way is at least equal to the overall length of the second implant.

The second hollow cutting tool is then threaded over the drill bit as far as the end of the latter to increase the diameter of the blind hole to 6 mm, which is substantially equal to the screwthread root diameter of the proximal self-tapping portion **30** of the body **3** of the second implant. The second hollow cutting tool and the first drill bit are then withdrawn from the epiphysis ES.

Two counterbores are then formed using the second counterboring tool. The second milling cutter guide is inserted into the 6 mm bone hole drilled previously and provides a guide for the third and fourth shape milling cutters. The third shape milling cutter bores a first counterbore 9.5 mm in diameter to a substantially greater depth equal to the length of the proximal self-tapping section **44** of the end-piece, whilst the fourth shape milling cutter bores a second, wider counterbore with a diameter of 11 mm to a depth substantially greater than the length of the distal self-tapping section **45** of the end-piece. The depth of the counterbores are determined by a stop ring similar to the ring BA which abuts against the external face of the trochanter when the counterbore is completed. The two milling cutter diameters of 9.5 mm and 11 mm are respectively substantially equal to the screwthread root diameters of the proximal and distal self-tapping sections **44** and **45** of the end-piece.

When the counterboring tools have been withdrawn, the body **3** of the second implant with the end-piece **4** threaded over the hexagonal cross-section portion **32** is placed in the two-counterbores blind hole in the bone formed in this way through the fracture FR2 in the upper femoral epiphysis ES as shown in FIG. **8**. The proximal notches **302** and the proximal self-tapping portion **30** of the body **3** bite into the bone and cut a screwthread in the bone from the internal shoulder between the 6 mm diameter long hole and the 9.5 mm diameter first counterbore. The proximal self-tapping portion **30** continues to move forward into the blind hole in the bone. Just before reaching the bottom of this hole, a first axial pressure is applied so that the proximal screwthreaded section **44** of the end-piece cuts a screwthread in the first counterbore, this section **44** having the same pitch as the body portion **30**. A second substantially higher pressure is then applied so that the distal screwthreaded section **45** of the end-piece cuts a screwthread with a greater pitch in the second counterbore. The screwthread cutting operations are effected using the hexagonal-end key C1 which cooperates with the internal distal section **42** of the end-piece, the proximal internal section **40** of which is engaged around the hexagonal cross-section portion **32** of the body **3**.

With the self-tapping body portion **30** installed at the bottom of the hole in the femoral head TE and the end-piece **4** immobilized in the trochanter TR in this way, the second key is screwed onto the distal body portion **33**. Traction is applied in the distal direction, longitudinally of the body of the second implant, by means of the second key so as to pull the femoral head TE fragment against the trochanter TR and thus close up the fracture.

After withdrawal of the second key the spring **5** is picked up with the tweezers and inserted into the smooth intermediate section **41** inside the end-piece, bearing on the shoulder **43**.

The plug **6** is screwed by means of a screwdriver onto the distal body portion **33** of the body **3** so that it compresses the spring **5**. The spring **5** therefore constitutes damper means adapted to push the end-piece **4** in the proximal direction and the body **3** in the distal direction, and procures compression at the fracture FR2, i.e., permanent and progressive traction of the femoral head TE in which the body **3** is anchored by the self-tapping portion **30** against the trochanter TR in which the end-piece **4** is anchored by the self-tapping sections **44** and **45**, unscrewing being impossible. This compression stabilizes the fracture to favor faster consolidation of the fracture.

Pseudo-arthrosis of a sub-capital transcervical fracture of the neck of the femur, even with an oblique Powles angle, can be treated using the second implant of the invention. Because the latent expansion of the spring **51** pushes the end-piece in the proximal direction and the body **3** in the distal direction, the second implant procures dynamic compression of the focus of the pseudo-arthrosis.

This compression can be complemented by using at least one first implant of the invention. Referring to FIG. **9**, two first implants 1_1 and 1_2 are disposed above and under the previous second implant **3** substantially in the same plane, as perpendicular as possible to the plane PS of the pseudo-arthrosis.

The pseudo-arthrosis can be treated without using pedicular grafting and without ostetomy because of the dynamic compression of the pseudo-arthrosis associated with the bone generating features of the implants, the angiogenic capability of the tubular portions **13** and **31** and the osteogenic covering on their external surfaces.

With this type of indication, a triangular arrangement enables immediate post-surgery load bearing. This arrangement is achieved by fitting a second implant of the invention to procure axial dynamic compression in the femoral neck CO associated with two first implants of the invention, one of which is oblique from bottom to top and the other of which is substantially horizontal and extends from front to rear.

A third osteosynthesis implant of the invention is shown in FIGS. **10**, **11** and **12** and comprises an elongate rectilinear body **3***a* of generally stud bolt-like cylindrical shape, a cylindrical distal end-piece **7** with a base and an external screwthread, containing a helical spring **5***a* and a screwthreaded hollow plug **6***a*, and a diaphysis plate **8**.

The longitudinal rectilinear body **3***a* is similar to the elongate rectilinear body **3** of the second implant shown in FIGS. **6** and **7**, but is longer than the latter so that its screwthreaded distal portion **33***a* projects from the external face of the epiphysis. Thus the body **3***a* comprises from its proximal end towards its distal end, a proximal self-tapping screwthreaded tubular portion **30***a*, a perforated smooth tubular portion **31***a*, a hexagonal cross-section operating portion **32***a* and finally a screwthreaded distal portion **33***a*. A blind internal revascularization conduit with a proximal mouth and plural radial orifices **341***a* in the smooth tubular portion **31***a*, as in the first and second implants of the invention, is formed in the proximal portion **30***a* and the smooth portion **31***a*.

As in the body of the first implant, the smooth tubular portion **31***a* has an outside diameter of 5.4 mm to 5.5 mm after thermal deposition.

As shown in FIG. **12**, the distal end-piece **7** comprises an internal conduit made up of first, second, third and fourth sections **70** through **73** having progressively larger transverse cross-sections from the proximal end towards the distal end of the end-piece.

The first section **70** is the longest and constitutes the proximal section of the internal conduit in the end-piece **4**. The section **70** is cylindrical with a circular cross-section substantially larger than the greatest width of the hexagonal cross-section of the operating portion **32***a* of the body **3***a*.

The second section **71** has a six-flats cross-section complementary to the hexagonal cross-section of the oper-

ating portion 32*a* of the body 3*a* and extends over a length less than the length of the operating portion 32*a* of the body 3*a* so that the body portion 32*a* can slide axially in the end-piece section 71 when the end-piece 7 is fixed into the femoral trochanter TR to pull the body 3*a* anchored into the femoral head TE by the proximal self-tapping portion 30*a* in the distal direction. As in the second implant, the polygonal cross-section sliding coupling between the body portion 32*a* and the section 71 also enables screwing of the proximal self-tapping portion 30*a* of the body 3*a* together with a screwthreaded portion on the periphery of the end-piece 7, in the bone.

The sections 71, 72 and 73 in the end-piece 7 have similar functions to those of the sections 40, 41 and 42 in the end-piece 4.

The section 72 is a smooth cylindrical section between the sections 71 and 73. The diameter of the smooth section 72 is greater than the greatest width of the hexagonal cross-section of the section 71 in the end-piece but substantially equal to the smallest width of the hexagonal cross-section of the distal section 73. All of the helical spring 5*a* and at least part of the plug 6*a* are housed in the intermediate end-piece section 72. The proximal end of the spring 5*a* is pressed against an internal shoulder between the sections 71 and 72 by the thrust exerted by the plug 6*a* applied against the distal end of the spring 5*a*. The spring 5*a* is preferably coated with a plastics material like the spring 5.

The third section 73 of the end-piece 7 has a hexagonal cross-section and is located at the distal end of the end-piece to receive the six-flats end of the previously mentioned key C1. When the section 71 of the end-piece 7 is threaded over the operating section 32*a* of the body 3*a*, the distal screwthreaded section 33*a* of the body 3*a* passes freely through the two internal conduit sections 72 and 73 of the end-piece. To push the spring 5*a* into its housing 72, the plug 6*a* is screwed onto the distal screwthreaded body portion 33*a*.

The screwthreaded plug 6*a* is similar to the plug 6 and can be moved a few millimeters in the axial direction in the end-piece 7 by the compressed spring 5*a*, being guided in the smooth section 72. The plug 6*a* has a slot 61*a* at its distal end so that it can be screwed around the distal screwthreaded portion 33*a* of the body 3*a* to compress the spring 5*a* between the proximal face of the spring 5*a* and the shoulder between the proximal section 72 and the smooth intermediate section 71 inside the end-piece 7.

As also shown in FIG. 12, the periphery of the end-piece 7 has a long proximal self-tapping screwthreaded anchor section 74 extending three-quarters the length of the end-piece and similar to the second screwthreaded section 45 and consequently having a diameter and/or a pitch different from those of the anchor portion 30*a* of the body 3*a*. The screwthreaded anchor section 74 has a surface treatment similar to that of the body 1.

The end-piece 7 also has at the periphery a distal thin circular base 75 and a smooth cylindrical section 76 situated between the base and the anchor section 74. The diameter of the smooth section 76 is greater than the outer diameter of the anchor section 74. The base 75 and the section 76, which are not included in the second implant, cooperate with the diaphysis plate 8.

The diaphysis plate 8 comprises, in the lower part, an elongate rectilinear lower anchor portion 80 to be implanted along an external face of the diaphysis of the femur and, in the upper part, an upper guide bearing portion 81.

Three holes 82 are formed in the anchor portion 80. The holes 42 extend substantially perpendicular to the faces of the portion 80 and are longitudinally aligned on the latter to receive anchor screws 83 with clearance.

As seen in FIG. 11, the diaphysis face 84 of the anchor portion has a concave cross-section to mate with the convex cross-section of the femoral diaphysis.

The guide and bearing portion 81 is a truncated cylindrical shank oblique to the longitudinal axis of the anchor portion 80. The axis of the shank 81 towards the trochanter TR is at an angle A of about 120° to 140° to the anchor portion 80. The proximal inclined base 85 of the shank 81 is also transversely concave, extending the diaphysis face 84, and has a convex longitudinal end 86 that substantially follows the concave curved profile in a median-lateral plane of the femoral epiphysis, at the base of the trochanter TR. The cylindrical shank 81 has a spot facing 88 of an axial smooth bore 89 in the inside of a distal base 87 perpendicular to the shank axis. The spot facing 88 and the bore 89 receive the thin base 75 and the distal cylindrical section 76 of the end-piece 7, respectively, which slide in them. The axial length of the spot facing 88 and of the bore 89, i.e., the shortest distance between the bases 87 and 85 of the shank 81 situated at the same end as the anchor portion 80, is substantially greater than the axial length of the base 75 and of the section 76 so that the latter are completely housed within the shank 81.

In the spot facing 88 there are provided means 9 for damping micro-displacement between the end-piece 7 anchored under the trochanter TR and the diaphysis plate 8. The damping means 9 attenuates any lever effect between the plate 8 and the combination of the body 3*a* and end-piece 7 due to microslipping of bone fragments at the focus of the fracture FR3. The damping means 9 comprises at least one washer 90 made from a damping material, such as an elastomer or polyurethane or silicone rubber, threaded over the smooth section 76. In the embodiment shown in FIG. 10 the washer 90 is sandwiched between two metal washers 91 and 92 that are preferably bonded by heat to the washer 90; this assembly of washers 90, 91 and 92 is threaded over the section 76 and clamped to the distal base of the section 76, in the spot facing 88, between the distal thin base 75 of the end-piece 7 and the bottom of the spot facing 88. In a different embodiment, the washer assembly includes only a damping material washer 90 and a single metal washer 91 or 92.

The third implant is preferentially used for sub-trochanter fractures FR3. It is implanted in the following manner.

The femoral plate 8 is fixed to the diaphysis face of the femur, locating the guide and bearing portion 81 on the sub-trochanter bend. The three anchor screws 83 are screwed into the femur through the plate holes 82, if necessary into pilot holes previously bored in the femur, up to clamp the plate 8 against the femoral diaphysis.

A cylindrical guide having an inside diameter substantially equal to that of a drill bit is slid into the bore 89.

The drill bit, longer than the body 3*a*, is introduced into the upper epiphysis ES of the femur, for example by rotating it by hand, through the aforementioned cylindrical guide, the trochanter TR, the fracture FR3, the neck CO of the femur and finally part of the femoral head TE to form a blind hole substantially perpendicular to the fracture FR3. The depth and the direction of this hole are monitored by X-rays so that the length bored in this phase is substantially equal to the length of the portions 30*a*, 31*a* and 32*a* of the body 3*a*.

After removing the previously mentioned cylindrical guide, a hollow cutting tool is then threaded over the first drill bit as far as the end of the latter to enlarge the blind hole to a diameter that is substantially equal to the screwthread root diameter of the proximal self-tapping portion 30*a* of the body 3*a* of the third implant. The above mentioned drill bit and the second cutting tool are then withdrawn from the epiphysis ES.

A cylindrical milling guide is inserted into the long hole just bored in the bone, and guides a shape milling cutter to bore a counterbore having a diameter equal to the screwthread root diameter of the self-tapping section 74 of the end-piece, to a depth substantially equal to the length of

the section 74. The depth of the counterbore is determined by a stop ring, similar to the ring BA (FIG. 3), which abuts against the external base 87 of the plate shank 81 when the end of the counterbore is reached. This counterbore may not be necessary if the diameter of the end-piece section 74 is substantially equal to that of the body portion 30*a*.

When the counterboring tools have been withdrawn, the body 3*a* of the third implant with the end-piece 7 threaded over the hexagonal cross-section portion 32*a* and with the assembly of washers 90, 91 and 92 threaded over the smooth end-piece section 76 is placed in the counterbored blind hole in the bone formed in this way through the fracture FR3 in the femoral upper epiphysis ES, as shown in FIG. 10. Proximal notches 302*a* and the self-tapping screwthread of the proximal portion 30*a* of the body 3*a* bite into the bone and cut a screwthread into the bone from the bottom of the counterbore. A proximal self-tapping portion 30*a* continues to move forward into the blind hole in the bone. Just before the portion 30*a* reaches the bottom of this hole, a first axial pressure is applied so that proximal notches 77 and the screwthread of the self-tapping section 74 of the end-piece 7 bite into and cut a screwthread into the counterbore in the bone. The section 74 can have the same screwthread pitch as the body portion 30*a* or preferably a larger pitch. The screwthread cutting operations are carried out using the hexagonal end key C1 which cooperates with the internal distal section 73 of the end-piece 7 the internal hexagonal cross-section portion 71 of which is engaged around the hexagonal cross-section portion 32*a* of the body 3*a*.

With the self-tapping body section 30*a* installed at the bottom of the hole in the bone in the femoral head TE and the end-piece 7 immobilized in the trochanter TR by the screwthreaded section 74 in this way, a second special key, similar to the blind screwthread key already used for the second implant, is screwed onto the distal body portion 33*a*. Traction is applied by means of the second key in the distal direction, longitudinally of the body 3*a*, to pull the femoral head TE fragment against the trochanter TR and thus to close up the fracture FR3.

After withdrawal of the second key, the spring 5*a* is picked up with the tweezers and inserted into the smooth section 72 inside the end-piece, bearing against the shoulder between the sections 72 and 71.

The plug 6*a* is screwed by means of a screwdriver onto the distal body portion 33*a* of the body 3*a* to compress the spring 5*a*. This compression procures permanent and progressive traction of the femoral head TE in which the body 3*a* is anchored by the self-tapping portion 30*a* against the trochanter TR in which the end-piece 7 is anchored by the self-tapping section 74, with unscrewing impossible, at the level of the fracture FR3 and in particular in the trochanter and sub-trochanter regions. The compression is distributed along the femoral diaphysis by application of the plate anchor portion 80 against the diaphysis, this distribution being notably effective when the forces applied in a sub-trochanter fracture FR3 are high. Relative to the seating of the implant on the diaphysis, the lever effect due to lateral microdisplacements and vibrations are attenuated by the retention of the distal end 76 of the end-piece 7 in the upper shank 81 and the damping washer means 9 accommodated in the shank spot facing 88. The body 3*a* of the implant is held axially, preventing intra-cephalic movement. The distribution of compression combined with the attenuation of microdisplacements enhances rapid consolidation of the fracture.

What we claim is:

1. An implant for osteosynthesis of a fracture between first bone fragment and a second bone fragment, comprising:

(a) an elongate implant body having a proximal end and a distal end, said implant body containing a longitudinal conduit extending from an opening in said proximal end toward said distal end, said body also containing a plurality of longitudinally spaced through openings extending radially outwardly from said conduit, said body proximal end being adapted for insertion within alined bores formed in the first and second bone fragments on opposite sides of the fracture; and

(b) first self-tapping means arranged at one end of said body for connecting said body one end with the associated bone fragment.

2. Arm implant as claimed in claim 1, comprising a plug located in said distal end of said body and obstructing said longitudinal conduit.

3. The implant as claimed in claim 2 wherein said distal end of said longitudinal conduit comprises a screwthread into which a screwthreaded shank of said plug is screwed.

4. The implant as claimed in claim 1 wherein said distal end of said conduit comprises a counterbore opening to the exterior of said body and having a polygonal cross-section to receive a complementary cross-section end of a key for screwing said body into a hole in said first bone fragment and second bone fragment.

5. The implant as claimed in claim 1 wherein said self-tapping portion is located at said distal end of said body to be implanted in said second bone fragment.

6. The implant as claimed in claim 5 wherein said self-tapping portion comprises two screwthreaded sections having different screwthreads.

7. The implant as claimed in claim 5 wherein said self-tapping portion includes at least one distal longitudinal notch for starting screwthread cutting.

8. The implant as claimed in claim 1 wherein said self-tapping portion comprises a proximal screwthreaded section and a distal screwthreaded section, said distal screwthreaded section having at least one of pitch and nominal diameter respectively greater than the respective one of pitch and nominal diameter of said proximal screwthreaded section.

9. The implant as claimed in claim 1 wherein said self-tapping portion is located at the proximal end of said body to be installed in said first bone fragment.

10. The implant as claimed in claim 9 wherein said self-tapping portion includes at least one distal longitudinal notch for starting screwthread cutting.

11. Implant means as defined in claim 1, wherein said first self-tapping means is arranged at said proximal end of said implant body; and further including:

(c) a tubular end-piece concentrically mounted for sliding movement on an intermediate portion of said implant body between the ends thereof;

(d) second self-tapping means mounted on said end-piece for connecting said end piece with the other of the bone fragments; and

(e) damping means connected with the other end of said implant body for biasing said end piece toward said proximal end of said implant body.

12. Implant means as defined in claim 11, and further including:

(f) a diaphysis plate containing a through opening in which said end-piece is mounted, said end piece having an external flange portion that limits the extent of travel of said end-piece toward the implant body proximal end; and

(g) means for securing said diaphysis plate to the second bone fragment.

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